

# EUROFOETUS

Randomized controlled trial on TTS  
and  
Observational study on TTS

## Clinical Record Forms



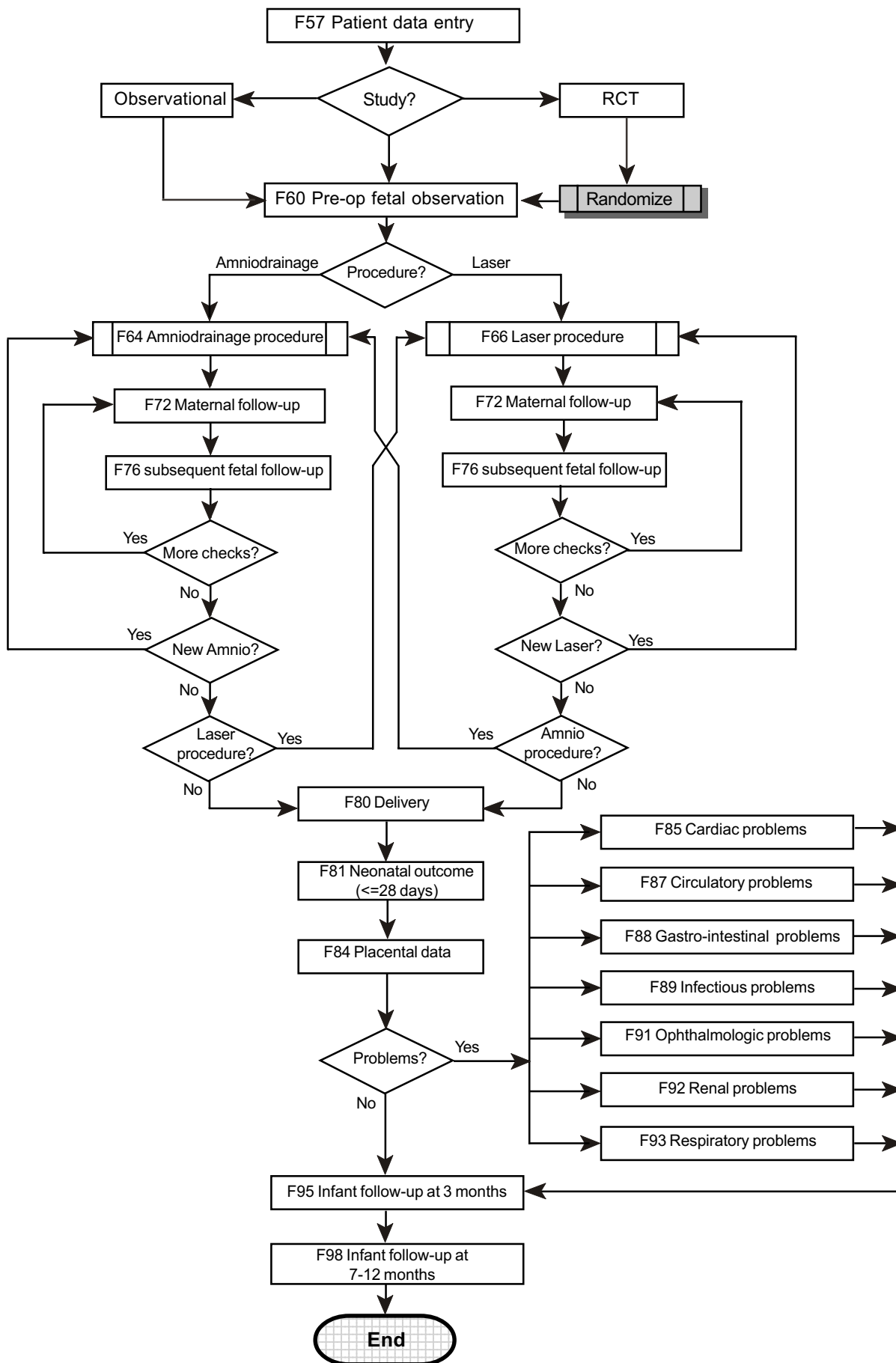
Patient initials:

Patient ID:

Euroforms 20 April 1999 Version 3.5

Please send these forms to:  
**Eurofoetus, c/o Dr. Jan Deprest**  
**Dept. of Obstetrics and Gynaecology**  
**U.Z. Leuven**  
**B - 3000 Leuven**  
**Belgium**

## Sequential order for completion of forms



Study: **Observational study on TTS** - Surgeon:

Patient:

**Randomized Controlled Trial (RCT) on TTS**

Underline or circle the applicable study

## F57 Patient data entry

All fields with an asterisk (\*) are mandatory fields.

<p><b>01. Patient initials:</b></p> <p><input type="text"/> <input type="text"/> <input type="text"/></p> <p>Please enter the patient initials. These will be used in combination with a sequential number attributed by the program to uniquely identify the patient.</p>	<p><b>02* Patient birth date:</b> (dd-mmm-yyyy)</p> <p><input type="text"/></p>
<p><b>03* Estimated date of delivery (EDD):</b></p> <p>Calculated either on last menstrual period, or on ultrasound, (dd-mmm-yyyy)</p> <p><input type="text"/></p>	<p><b>04* Date diagnosis established:</b></p> <p>(dd-mmm-yyyy).</p> <p><input type="text"/></p>
<p><b>05. Gestational age (GA-D) at diagnosis:</b></p> <p><input type="text"/></p> <p>The program will calculate the GA. However, the maximum GA should be less than 26.0 weeks. If the GA is equal to or more than 26.0 weeks, stop completing the form.</p>	<p><b>06* Monochorionic pregnancy:</b></p> <p><input type="radio"/> No <input type="radio"/> Yes</p> <p>Only monochorionic pregnancies are eligible for this study.</p> <p><b>07* Number of fetuses:</b> <input type="text"/></p>
<p><b>08* Major fetal anomaly:</b></p> <p><input type="radio"/> No <input type="radio"/> Yes</p> <p><b>10. Specify fetal anomaly:</b></p> <p>Completion of this field is compulsory if the previous field is answered yes.</p> <p><input type="text"/></p>	<p><b>09* Ruptured membranes:</b></p> <p><input type="radio"/> No <input type="radio"/> Yes</p> <p><b>11* Maternal condition mandating delivery:</b></p> <p><input type="radio"/> No <input type="radio"/> Yes</p>
<b>US inclusion data</b>	
<p><b>12* Date US observation:</b> (dd-mmm-yyyy).</p> <p><input type="text"/></p>	<p><b>13. Gestational age (GA-US) at US observation:</b></p> <p><input type="text"/></p> <p>The program will calculate the GA US.</p>
<p><b>14* Deepest vertical pool (DVP) of amniotic fluid (AF) in the larger sac (recipient):</b></p> <p><input type="text"/></p> <p>DVP must be as follows: at &lt;20 weeks, &gt;=60mm from 20 to 22 weeks, &gt;= 80mm from 23 to 25 weeks, &gt;=120mm</p>	<p><b>15* Deepest vertical pool (DVP) of AF in the smaller sac (donor):</b></p> <p><input type="text"/></p> <p>Only DVP&lt;=20mm can enter this study.</p>
<p><b>16. Distended bladder recipient:</b></p> <p><input type="radio"/> No <input type="radio"/> Yes</p> <p>The bladder of the recipient should be distended during most of the examination.</p>	<p><b>17. Collapsed bladder donor:</b></p> <p><input type="radio"/> No <input type="radio"/> Yes</p> <p>(During most of the examination.)</p>
<p><b>18. Placental location (predominant):</b></p> <p><input type="radio"/> anterior</p> <p><input type="radio"/> posterior</p> <p><input type="radio"/> fundal</p> <p><input type="radio"/> previa</p> <p>Please check one.</p>	<p><b>19. Date of completion of this form:</b></p> <p>(dd-mmm-yyyy).</p> <p><input type="text"/></p>

Study: **Observational study on TTS** - Surgeon:   
**Randomized Controlled Trial (RCT) on TTS**

Patient:

Underline or circle the applicable study

## F60 Fetal observation prior to first intervention (page 1)

<b>01. Date of this observation:</b> (dd-mmm-yyyy)	<input style="width: 100%;" type="text"/>	
	<b>DONOR</b>	<b>RECIPIENT</b>
<b>02. Gestational age at observation date (GA):</b> The program will calculate the GA. However, the maximum GA should be less than 26.0 weeks. If the GA is equal to or more than 26.0 weeks, stop completing the form.	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
<b>03. Fetus alive:</b>	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes
<b>Biometry US measurements</b>	<b>DONOR</b>	<b>RECIPIENT</b>
<b>04. Biparietal diameter BPD:</b> (range 10-200mm)	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
<b>05. Head circumference HC:</b> (range 20-500mm)	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
<small>You have the choice of completing this field or the following two fields. Either AC, or APD plus ATD.</small>		
<b>06. Abdominal circumference AC:</b> (range 20-600mm)	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
<b>07. Abdominal anterior-posterior diameter APD:</b> (range 10-250mm)	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
<b>08. Abdominal transversal diameter ATD:</b> (range 10-250mm)	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
<b>09. Femur length:</b> (range 5-100mm)	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
<b>10. Thorax/heart circumference ratio:</b> (range 0.01-1.00)	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
<b>11. Fetal bladder filled:</b>	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes
<b>12. Any other fetal abnormality:</b>	<b>Donor</b>	<b>Recipient</b>
<input style="width: 100%; height: 100%;" type="text"/>	<input style="width: 100%; height: 100%;" type="text"/>	
<b>13. Left anterior cerebral ventricle:</b> (range: 1-100mm)	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
<b>14. Left posterior cerebral ventricle:</b> (range: 1-100mm)	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
<b>15. Left hemisphere:</b> (range: 1-100mm)	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>

Study: **Observational study on TTS** - Surgeon:   
**Randomized Controlled Trial (RCT) on TTS**

Patient:

Underline or circle the applicable study

## F60 Fetal observation prior to first intervention (page 2)

	DONOR	RECIPIENT
<b>16. Right anterior cerebral ventricle:</b> (range 1-100mm)	<input type="text"/>	<input type="text"/>
<b>17. Right posterior cerebral ventricle:</b> (range 1-100mm)	<input type="text"/>	<input type="text"/>
<b>18. Right hemisphere:</b> (range 1-100mm)	<input type="text"/>	<input type="text"/>
<b>19. Ascites:</b> Please check one only.	<input type="radio"/> No <input type="radio"/> + <input type="radio"/> ++ <input type="radio"/> +++	<input type="radio"/> No <input type="radio"/> + <input type="radio"/> ++ <input type="radio"/> +++
<b>20. Pleural effusion:</b> Please check one only.	<input type="radio"/> No <input type="radio"/> + <input type="radio"/> ++ <input type="radio"/> +++	<input type="radio"/> No <input type="radio"/> + <input type="radio"/> ++ <input type="radio"/> +++
<b>21. Pericardial effusion:</b> Please check one only.	<input type="radio"/> No <input type="radio"/> + <input type="radio"/> ++ <input type="radio"/> +++	<input type="radio"/> No <input type="radio"/> + <input type="radio"/> ++ <input type="radio"/> +++
<b>22. Skin edema:</b> Please check one only.	<input type="radio"/> No <input type="radio"/> + <input type="radio"/> ++ <input type="radio"/> +++	<input type="radio"/> No <input type="radio"/> + <input type="radio"/> ++ <input type="radio"/> +++
<b>23. AF deepest vertical pocket:</b> (mm)	<input type="text"/>	<input type="text"/>
<b>Doppler measurements</b>	<b>DONOR</b>	<b>RECIPIENT</b>
<b>24. Umbilical artery pulsatility index:</b> (PI, range 0.10 till 10.00)	<input type="text"/>	<input type="text"/>
<b>25. Absence of end diastolic flow (AEDF):</b> Please check one only.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Reversed	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Reversed
<b>26. Median cerebral artery pulsatility index:</b> (PI, range 0.10 till 10.00)	<input type="text"/>	<input type="text"/>
<b>27. Fetal aorta pulsatility index:</b> (PI, range 0.10 till 10.00)	<input type="text"/>	<input type="text"/>
<b>28. Inferior vena cava pulsatility index:</b> (PI, range 0.10 till 10.00)	<input type="text"/>	<input type="text"/>
<b>29. Ductus venosus pulsatility index:</b> (PI, range 0.10 till 10.00)	<input type="text"/>	<input type="text"/>
<b>Echocardiography measurements</b>		
<b>30. Tricuspid regurgitation:</b> Please check one only.	<input type="radio"/> No <input type="radio"/> Early systolic <input type="radio"/> Holosystolic	<input type="radio"/> No <input type="radio"/> Early systolic <input type="radio"/> Holosystolic

Study: **Observational study on TTS** - Surgeon:   
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Patient:

## F64 Amniodrainage procedure

01. Date of procedure: (dd-mmm-yyyy)

02. Which number of procedure in this patient:  
(range 1-20)

03. Needle used:

Please indicate size in gauges.

04. Insertion site:

Please check all applicable.

- Upper right quadrant  
 Upper left quadrant  
 Lower right quadrant  
 Lower left quadrant

05. Transplacental insertion:

As observed at any point during the procedure.

- No  Yes

06. Amniotic fluid color:

Please check all applicable.

- Clear  
 Blood stained (fresh)  
 Blood stained (old)  
 Meconium  
 Turbid

07. Bleeding at insertion:

- No  Yes

08. Amniotic fluid stored:

- No  Yes

09. Amniotic fluid drained:

(in mL, range 10-10,000mL)

10. Duration of procedure:

(in min, range 1-300 min)

11. Maternal discomfort during procedure:

- No  Yes

Study: **Observational study on TTS** - Surgeon:   
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Underline or circle the applicable study

Patient:

## F66 Laser procedure (page 1)

01. Date of procedure: (dd-mmm-yyyy)

02. Which number of procedure in this patient:  
(range 1-9)

03. Anesthesia:

Please check all applicable.

- No
- Local
- Local plus sedation
- Loco-regional
- General

04. Scope used:

Please check all applicable.

- Storz 2.0 mm fibre scope
- Storz 2.3 mm rod lens
- Storz 1.2 mm fibre scope
- Olympus 1.9 mm rod lens
- Any other, specify type and diameter

05. Outer diameter sheath/cannula:

(in mm, range 1-6 mm)

06. Number of port entries during this procedure:

1  2  3  4

07. Insertion site:

Please check all applicable.

- Upper right quadrant
- Upper left quadrant
- Lower right quadrant
- Lower left quadrant

08. Insertion technique:

- Percutaneous
- Minilaparotomy (<3cm)
- Laparotomy

09. Transplacental insertion:

As observed at any point during the procedure

No  Yes

10. Amniotic fluid color:

Please check all applicable and at least one box.

- Clear
- Blood stained (fresh)
- Blood stained (old)
- Meconium
- Turbid

Study: **Observational study on TTS** - Surgeon:   
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Patient:

Underline or circle the applicable study

## F66 Laser procedure (page 2)

11. Intra-amniotic bleeding at entry:  No  Yes

12. Membrane dislodgement at entry:  No  Yes

13. Other complications at entry:  No  Yes

14. Specify complications at entry:

Please complete if previous question is answered yes.

15. Visualisation during procedure:

Poor                Good

This is a semiquantitative score; please check a box at a point where you believe it reflects your satisfaction with visualisation during the procedure, from extremely poor (left) to extremely good (right).

16. Technical performance during procedure:

Poor               Good

Please check a box at a point where you believe it reflects your satisfaction with the procedure from a technical point of view, from extremely poor (left) to extremely good (right).

If anastomoses were counted fetoscopically, please list number.

17a. Number of AV anastomoses:   
from donor to recipient  
(range 1-20)

17b. Number of AV anastomoses:   
from recipient to donor  
(range 1-20)

18. Number of AA anastomoses:   
(range 1-20)

19. Number of VV anastomoses:   
(range 1-20)

20. Technique of coagulation:  Selective coagulation of anastomoses  
Please check all applicable.  Along membranes  
 Combination

21. Number of coagulated vessels:   
(range 1-99)

22. Total #Joules used:   
(range 100-9,999)

23. Fibre diameter:   
(in  $\mu\text{m}$ , range 200-999)

Study: **Observational study on TTS** - Surgeon:   
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Patient:

Underline or circle the applicable study

## F66 Laser procedure (page 3)

**24. Maximum energy used:**   
(in Watts, range 10-100)

**25. Total amnioinfusion volume:**   
(in mL, range 0-99,999)

**26. Total volume drained:**   
(in mL, range 0-99,999)

**27. Net amniotic fluid balance:**   
The program will calculate this field. It is the result of  
infused minus drained.

**28. Duration of procedure (skin-to-skin):**   
(in min, range 1-300)

**29. Intra-operative complications:**  No  Yes

**30. Specify complications or any other comment:**  
Please complete if previous question is answered yes.

**31. Fetal death during or within 24 hours following the procedure:**  No  Yes

**32. PPRM during procedure or first 24 hours:**  No  Yes

**33. Maternal discomfort during procedure:**  No  Yes

**34. Peri-operative medical therapy including tocolysis or antibiotics:**  
Please complete if applicable.

**35. Septostomy:**  Not done  
 Intentional  
 Not intentional

Study: **Observational study on TTS** - Surgeon:   
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Patient:

## F72 Maternal follow-up

01. Date of this observation: (dd-mmm-yyyy)

02. Ascites:

No  Yes

03. Intraoperative bleeding:

No  Yes

04. Preterm labour requiring tocolysis:

No  Yes

05. (P)PROM: (dd-mmm-yyyy)

If yes, enter the date of rupture.

06. Local infection:

No  Yes

07. Chorioamnionitis:

No  Yes

08. Other complications:

No  Yes

09. Specify other complications:

Study: **Observational study on TTS** - Surgeon:   
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Underline or circle the applicable study

Patient:

## F76 Subsequent fetal follow-up (page 1)

<b>01. Date of this observation:</b> (dd-mmm-yyyy)	<input style="width: 100%;" type="text"/>	
	<b>DONOR</b>	<b>RECIPIENT</b>
<b>02. Gestational age at observation date (GA):</b>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
<small>The program will calculate the GA. However, the maximum GA should be less than 26.0 weeks. If the GA is equal to or more than 26.0 weeks, stop completing the form.</small>		
<b>03. Fetus alive:</b>	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes
<b>03bis. Presumed date of fetal death:</b>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
<small>Please complete if previous question is answered no.</small>		
<b>Biometry US measurements</b>	<b>DONOR</b>	<b>RECIPIENT</b>
<b>04. Biparietal diameter BPD:</b> <small>(range 10-200mm)</small>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
<b>05. Head circumference HC:</b> <small>(range 20-500mm)</small>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
<small>You have the choice of completing this field or the following two fields. Either AC, or APD plus ATD.</small>		
<b>06. Abdominal circumference AC:</b> <small>(range 20-600mm)</small>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
<b>07. Abdominal anterior-posterior diameter APD:</b> <small>(range 10-250mm)</small>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
<b>08. Abdominal transversal diameter ATD:</b> <small>(range 10-250mm)</small>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
<b>09. Femur length:</b> <small>(range 5-100mm)</small>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
<b>10. Thorax/heart circumference ratio:</b> <small>(range 0.01-1.00)</small>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
<b>11. Fetal bladder filled:</b>	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes
<b>12. Any other fetal abnormality:</b>	<b>Donor</b>	<b>Recipient</b>
<input style="width: 100%; height: 100%;" type="text"/>	<input style="width: 100%; height: 100%;" type="text"/>	
<b>13. Left anterior cerebral ventricle:</b> <small>(range: 1-100mm)</small>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
<b>14. Left posterior cerebral ventricle:</b> <small>(range: 1-100mm)</small>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
<b>15. Left hemisphere:</b> <small>(range: 1-100mm)</small>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>

Study: **Observational study on TTS** - Surgeon:

Patient:

**Randomized Controlled Trial (RCT) on TTS**

Underline or circle the applicable study

## F76 Subsequent fetal follow-up (page 2)

	DONOR	RECIPIENT
<b>16. Right anterior cerebral ventricle:</b> (range 1-100mm)	<input type="text"/>	<input type="text"/>
<b>17. Right posterior cerebral ventricle:</b> (range 1-100mm)	<input type="text"/>	<input type="text"/>
<b>18. Right hemisphere:</b> (range 1-100mm)	<input type="text"/>	<input type="text"/>
<b>19. Ascites:</b> Please check one only.	<input type="radio"/> No <input type="radio"/> + <input type="radio"/> ++ <input type="radio"/> +++	<input type="radio"/> No <input type="radio"/> + <input type="radio"/> ++ <input type="radio"/> +++
<b>20. Pleural effusion:</b> Please check one only.	<input type="radio"/> No <input type="radio"/> + <input type="radio"/> ++ <input type="radio"/> +++	<input type="radio"/> No <input type="radio"/> + <input type="radio"/> ++ <input type="radio"/> +++
<b>21. Pericardial effusion:</b> Please check one only.	<input type="radio"/> No <input type="radio"/> + <input type="radio"/> ++ <input type="radio"/> +++	<input type="radio"/> No <input type="radio"/> + <input type="radio"/> ++ <input type="radio"/> +++
<b>22. Skin edema:</b> Please check one only.	<input type="radio"/> No <input type="radio"/> + <input type="radio"/> ++ <input type="radio"/> +++	<input type="radio"/> No <input type="radio"/> + <input type="radio"/> ++ <input type="radio"/> +++
<b>23. AF deepest vertical pocket:</b> (mm)	<input type="text"/>	<input type="text"/>
<b>Doppler measurements</b>	<b>DONOR</b>	<b>RECIPIENT</b>
<b>24. Umbilical artery pulsatility index:</b> (PI, range 0.10 till 10.00)	<input type="text"/>	<input type="text"/>
<b>25. Absence of end diastolic flow (AEDF):</b> Please check one only.	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Reversed	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Reversed
<b>26. Median cerebral artery pulsatility index:</b> (PI, range 0.10 till 10.00)	<input type="text"/>	<input type="text"/>
<b>27. Fetal aorta pulsatility index:</b> (PI, range 0.10 till 10.00)	<input type="text"/>	<input type="text"/>
<b>28. Inferior vena cava pulsatility index:</b> (PI, range 0.10 till 10.00)	<input type="text"/>	<input type="text"/>
<b>29. Ductus venosus pulsatility index:</b> (PI, range 0.10 till 10.00)	<input type="text"/>	<input type="text"/>
<b>Echocardiography measurements</b>		
<b>30. Tricuspid regurgitation:</b> Please check one only.	<input type="radio"/> No <input type="radio"/> Early systolic <input type="radio"/> Holosystolic	<input type="radio"/> No <input type="radio"/> Early systolic <input type="radio"/> Holosystolic
<b>32. Any additional information:</b> Any intervention, secondary to the first laser or amniodrainage procedure: - if laser: complete a new laser procedure form; - if amniodrainage: complete a new amniodrainage form; - if any other, such as intra-uterine transfusion, (additional) medical therapy, feticide or any other: describe in the text box to the right.	<input type="text"/>	

Study: **Observational study on TTS** - Surgeon:   
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Patient:

Underline or circle the applicable study

## F80 Delivery

<b>01. Date of delivery:</b> (dd-mmm-yyyy)	<input type="text"/>	
	<b>DONOR</b>	<b>RECIPIENT</b>
	<input type="text"/>	<input type="text"/>
<b>02. Fetus born alive:</b>	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes
<b>02bis. Presumed date of fetal death:</b> <small>Please complete if previous question is answered no.</small>	<input type="text"/>	<input type="text"/>
<b>03. Birth weight:</b> <small>(range 50-5,000grams)</small>	<input type="text"/>	<input type="text"/>
<b>04. First name:</b> <small>For identification purposes</small>	<input type="text"/>	<input type="text"/>
<b>05. Length in centimeters:</b> <small>(range 10-70)</small>	<input type="text"/>	<input type="text"/>
<b>06. Apgar score at 5 min:</b> <small>(range 0-10)</small>	<input type="text"/>	<input type="text"/>
<b>07. pH umbilical artery:</b> <small>(range 6.50-7.60)</small>	<input type="text"/>	<input type="text"/>
<b>08. pH umbilical vein:</b> <small>(range 6.50-7.60)</small>	<input type="text"/>	<input type="text"/>
<b>09. Cord Hb (hemoglobin):</b> <small>(in grams/dL)</small>	<input type="text"/>	<input type="text"/>

Study: **Observational study on TTS** - Surgeon:

Patient:

**Randomized Controlled Trial (RCT) on TTS**

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## F81 Neonatal Outcome (<= 28 days) (page 1)

<b>01. Date of this observation:</b> (dd-mmm-yyyy)	<input type="text"/>	
	<b>DONOR</b>	<b>RECIPIENT</b>
<b>02. Head circumference:</b> (in cm)	<input type="text"/>	<input type="text"/>
<b>03. Transfusion:</b>	<input type="radio"/> No <input type="radio"/> Blood <input type="radio"/> Plasma	<input type="radio"/> No <input type="radio"/> Blood <input type="radio"/> Plasma
<b>04. Ventilation:</b>	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes
<b>05. Total days of ventilation:</b> (1 to 99)	<input type="text"/>	<input type="text"/>
<b>06. Death:</b>	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes
<b>07. Date of death:</b> (dd-mmm-yyyy) Mandatory field if previous question is answered yes.	<input type="text"/>	<input type="text"/>
<b>08. Intraventricular hemorrhage (IVH):</b> (range 10-250mm)	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes
<b>09. Grade IVH:</b> - isolated germinal matrix hemorrhage - IVH with normal ventricular size - IVH with ventricular dilatation - IVH with parenchymal hemorrhage Please check one if the previous field is answered yes. <i>According to Papile's system of grading of severity (J Pediatr 1983; 273:273)</i>	<input type="radio"/> Grade I <input type="radio"/> Grade II <input type="radio"/> Grade III <input type="radio"/> Grade IV	<input type="radio"/> Grade I <input type="radio"/> Grade II <input type="radio"/> Grade III <input type="radio"/> Grade IV
<b>10. Leukomalacia:</b>	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes
<b>11. Grade leukomalacia:</b> - transient periventricular (PV) densities for more than 7 days - transient PV densities evolving into small localized frontoparietal cysts - PV densities evolving into extensive PV cystic lesions - densities extending into the deep white matter evolving into cystic lesions Please check one if the previous field is answered yes. <i>Scored according to de Vries et al (Beh Brain Res 1992; 19:1)</i>	<input type="radio"/> Grade I <input type="radio"/> Grade II <input type="radio"/> Grade III <input type="radio"/> Grade IV	<input type="radio"/> Grade I <input type="radio"/> Grade II <input type="radio"/> Grade III <input type="radio"/> Grade IV

Study: **Observational study on TTS** - Surgeon:  Patient:   
**Randomized Controlled Trial (RCT) on TTS**  
 Underline or circle the applicable study

## F81 Neonatal Outcome (<= 28 days) (page 2)

	DONOR	RECIPIENT
<b>12. Hypoxic-ischemic encephalopathy (HIE):</b> <i>A disturbance in cerebral function manifested in the first few days by altered level of consciousness, a disturbance in muscle tone and posture, and seizures, associated with signs of peripartum hypoxia (Prenat Neonat Med 1966; 1:160)</i>	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes
<b>13. Convulsions:</b>	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes
<b>14. Post-hemorrhagic hydrocephalus:</b>	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes
<b>15. Respiratory problems:</b> <small>(If yes, please complete the form 'Respiratory problems')</small>	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes
<b>16. Circulatory problems:</b> <small>(If yes, please complete the form 'Circulatory problems')</small>	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes
<b>17. Cardiac problems:</b> <small>(If yes, please complete the form 'Cardiac problems')</small>	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes
<b>18. Renal problems:</b> <small>(If yes, please complete the form 'Renal problems')</small>	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes
<b>19. Gastro-intestinal problems:</b> <small>(If yes, please complete the form 'Gastro-intestinal problems')</small>	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes
<b>20. Infectious problems:</b> <small>(If yes, please complete the form 'Infectious problems')</small>	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes
<b>21. Ophthalmologic problems:</b> <small>(If yes, please complete the form 'Ophthalmologic problems')</small>	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes

Study: **Observational study on TTS** - Surgeon:   
**Randomized Controlled Trial (RCT) on TTS**  
Underline or circle the applicable study

Patient:

## F84 Placental data

01. Date of this observation: (dd-mmm-yyyy)

02. Chorioamnionitis:

No  Yes

03. Cord insertion donor:

Central  
 Marginal  
 Velamentous

04. Cord insertion recipient:

Central  
 Marginal  
 Velamentous

05. Chorionicity:

Monochorionic  
 Dichorionic

06. Perfusion study confirming anastomoses:

Confirmed  
 Not confirmed  
 Not done

07. Any comments:

Study: **Observational study on TTS** - Surgeon:   
**Randomized Controlled Trial (RCT) on TTS**  
Underline or circle the applicable study

Patient:

## F85 Cardiac problems

01. Date of this observation: (dd-mmm-yyyy)

**DONOR**

**RECIPIENT**

02. Shock:

No  Yes

No  Yes

03. Persistent ductus arteriosus:

No  Yes

No  Yes

04. Congenital malformation:

No  Yes

No  Yes

05. Specify congenital malformation:

**Donor**

**Recipient**

06. Cardiac hypertrophy:

Diagnosis made with ultrasound by a pediatric cardiologist.

No  Yes

No  Yes

Not assessed

Not assessed

07. Other problems:

**Donor**

**Recipient**

Study: **Observational study on TTS** - Surgeon:   
**Randomized Controlled Trial (RCT) on TTS**

Underline or circle the applicable study

Patient:

## F87 Circulatory problems

<b>01. Date of this observation:</b> (dd-mmm-yyyy)	<input type="text"/>	
	<b>DONOR</b>	<b>RECIPIENT</b>
<b>02. Shock:</b>	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes
<b>03. Hypovolemia:</b>	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes
<b>04. Hydrops:</b>	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes
<b>05. Pulmonary hypertension:</b>	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes
<b>06. Other problems:</b>		
<b>Donor</b>	<b>Recipient</b>	
<input type="text"/>	<input type="text"/>	

Study: **Observational study on TTS** - Surgeon:   
**Randomized Controlled Trial (RCT) on TTS**

Patient:

Underline or circle the applicable study

## F88 Gastro-intestinal problems

<b>01. Date of this observation:</b> (dd-mmm-yyyy)	<input type="text"/>	
	<b>DONOR</b>	<b>RECIPIENT</b>
<b>02. Necrotic enterocolitis (NEC):</b>	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes
<b>03. Meconium ileus:</b>	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes
<b>04. Gastro-intestinal obstruction:</b>	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes
<b>05. Other problems:</b>		
<b>Donor</b>	<b>Recipient</b>	
<input type="text"/>	<input type="text"/>	

Study: **Observational study on TTS** - Surgeon:   
**Randomized Controlled Trial (RCT) on TTS**

Underline or circle the applicable study

Patient:

## F89 Infectious problems

<b>01. Date of this observation:</b> (dd-mmm-yyyy)	<input type="text"/>	
	<b>DONOR</b>	<b>RECIPIENT</b>
<b>02. Peripartal bacterial infection:</b> Confirmed by positive cultures	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes
<b>03. Type of infection and micro-organism/s isolated:</b> Please complete if previous field was answered yes.		
<b>Donor</b>	<b>Recipient</b>	
<input type="text"/>	<input type="text"/>	
<b>04. Viral infection:</b>	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes
<b>05. Specify viral infection:</b> Please complete if previous field was answered yes.		
<b>Donor</b>	<b>Recipient</b>	
<input type="text"/>	<input type="text"/>	
<b>06. Clinical sepsis without positive cultures:</b>	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes
<b>07. Other problems:</b>		
<b>Donor</b>	<b>Recipient</b>	
<input type="text"/>	<input type="text"/>	

Study: **Observational study on TTS** - Surgeon:   
**Randomized Controlled Trial (RCT) on TTS**

Underline or circle the applicable study

Patient:

## F91 Ophthalmologic problems

01. Date of this observation: (dd-mmm-yyyy)

**DONOR**

**RECIPIENT**

02. Retinopathy of prematurity:

No  Yes

No  Yes

03. Grade of retinopathy:

I Demarcation line between avascular and vascularized retina

Grade I

Grade I

II Ridge formation

Grade II

Grade II

III Grade II + extraretinal fibrovascular proliferation

Grade III

Grade III

IV Grade III + retinal detachment

Grade IV

Grade IV

Please check one if the previous field is answered yes.

Scored according to the Committee for Classification of Retinopathy of Prematurity (Arch Ophthalmol 1984; 102:1130)

04. Other problems:

**Donor**

**Recipient**

Study: **Observational study on TTS** - Surgeon:   
**Randomized Controlled Trial (RCT) on TTS**  
Underline or circle the applicable study

Patient:

## F92 Renal problems

<b>01. Date of this observation:</b> (dd-mmm-yyyy)	<input type="text"/>	
	<b>DONOR</b>	<b>RECIPIENT</b>
<b>02. Anuria/Oliguria:</b> Urine output <0.5ml/Kg/h for more than 6 hours	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes
<b>03. Polyuria:</b> Urine output >5ml/Kg/h for more than 6 hours	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes
<b>04. Creatinine &gt;1.5mg/dL:</b> Between day 2 and day 7 of neonatal life	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes
<b>05. Tubular dysfunction:</b>	<input type="radio"/> No <input type="radio"/> Yes	<input type="radio"/> No <input type="radio"/> Yes
<b>06. Other problems:</b>		
<b>Donor</b>	<b>Recipient</b>	
<input type="text"/>	<input type="text"/>	

Study: **Observational study on TTS** - Surgeon:   
**Randomized Controlled Trial (RCT) on TTS**

Underline or circle the applicable study

Patient:

## F93 Respiratory problems

01. Date of this observation: (dd-mmm-yyyy)

- |   | DONOR   | RECIPIENT   |
|---|---|---|
| 02. Respiratory distress syndrome:      | <input type="radio"/> No <input type="radio"/> Yes              | <input type="radio"/> No <input type="radio"/> Yes              |
| 03. Transient tachypnea of the neonate: | <input type="radio"/> No <input type="radio"/> Yes              | <input type="radio"/> No <input type="radio"/> Yes              |
| 04. Meconium aspiration:                | <input type="radio"/> No <input type="radio"/> Yes              | <input type="radio"/> No <input type="radio"/> Yes              |
| 05. Pulmonary oedema:                   | <input type="radio"/> No <input type="radio"/> Yes              | <input type="radio"/> No <input type="radio"/> Yes              |
| 06. Congenital pneumonia:               | <input type="radio"/> No <input type="radio"/> Yes              | <input type="radio"/> No <input type="radio"/> Yes              |
| 07. Hypoplastic lungs:                  | <input type="radio"/> No <input type="radio"/> Yes              | <input type="radio"/> No <input type="radio"/> Yes              |
| 08. Pneumothorax:                       | <input type="radio"/> No <input type="radio"/> Yes              | <input type="radio"/> No <input type="radio"/> Yes              |
| 09. Chronic lung disease (CLD):         | <input type="radio"/> No <input type="radio"/> Yes              | <input type="radio"/> No <input type="radio"/> Yes              |
| 10. Grade CLD:                          | <input type="radio"/> Grade I<br><input type="radio"/> Grade II | <input type="radio"/> Grade I<br><input type="radio"/> Grade II |

Defined as oxygen dependence for more than 28 days after birth with an abnormal X-ray appearance.

I Homogeneous or patchy ill-defined opacification of the lungs without coarse reticulation.

II Classical appearance of bronchopulmonary dysplasia: coarse reticulation characterized by streaky density interspersed with small cystic translucencies.

Please check one if the previous field is answered yes. *According to Hyde et al (Arch Dis Child 1983; 64:448)*

11. Other problems:

Donor

Recipient

Study: **Observational study on TTS** - Surgeon:   
**Randomized Controlled Trial (RCT) on TTS**

Patient:

Underline or circle the applicable study

### F95 Infant follow-up at 3 months (page 1)

**01. Date of completion of this form:**   
(dd-mmm-yyyy)

**02. Death:** **DONOR**  No  Yes **RECIPIENT**  No  Yes

**03. Date of death:** (dd-mmm-yyyy)    
Mandatory field if previous question is answered yes.

Please leave blank non-applicable fields in case of death of one infant.

**04. Weight:**    
(range 1,000-9,999 grams)

**05. Length:**    
(range 25-99 cm)

**06. Head circumference:**    
(in cm)

**07. Clinical examination:**  
1 Normal  1  1  
2 Residual problems important for the future  2  2

**08. Specify problems:**  
Please complete this field if the answer to the previous question is answered 'Residual problems'.

**Donor**

**Recipient**

**09. Neurologic examination:** **DONOR**  Normal  Abnormal **RECIPIENT**  Normal  Abnormal

**10. Specify neurologic abnormality:**  
Please complete this field if the answer to the previous question is answered 'Abnormal'.

**Donor**

**Recipient**

**11. MRI:**  Normal  Abnormal  Not performed  Normal  Abnormal  Not performed

**Study:** **Observational study on TTS** - **Surgeon:**  **Patient:**   
**Randomized Controlled Trial (RCT) on TTS**  
Underline or circle the applicable study

## F95 Infant follow-up at 3 months (page 2)

### 12. Specify MRI abnormality:

Please complete this field if the answer to the previous question is answered 'Abnormal'.

**Donor**

**Recipient**

## F98 Infant follow-up at 7-12 months (page 1)

<p><b>01. Date of completion of this form:</b> (dd-mmm-yyyy) <input style="width: 100%;" type="text"/></p>		
<p><b>02. Death:</b></p>	<p><b>DONOR</b></p> <p><input type="radio"/> No <input type="radio"/> Yes</p>	<p><b>RECIPIENT</b></p> <p><input type="radio"/> No <input type="radio"/> Yes</p>
<p><b>03. Date of death:</b> (dd-mmm-yyyy) Mandatory field if previous question is answered yes.</p>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
<p><b>Please leave blank non-applicable fields in case of death of one infant.</b></p>		
<p><b>04. Weight:</b> (range 1,000-9,999 grams)</p>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
<p><b>05. Length:</b> (range 25-99 cm)</p>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
<p><b>06. Head circumference:</b> (in cm)</p>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
<p><b>07. Clinical examination:</b></p> <p>1 Normal <span style="margin-left: 100px;"><input type="radio"/> 1</span> <span style="margin-left: 100px;"><input type="radio"/> 1</span></p> <p>2 Residual problems important for the future <span style="margin-left: 100px;"><input type="radio"/> 2</span> <span style="margin-left: 100px;"><input type="radio"/> 2</span></p>		
<p><b>08. Specify problems:</b> Please complete this field if the answer to the previous question is answered 'Residual problems'.</p>		
<p><b>Donor</b></p> <div style="border: 1px solid black; height: 60px; width: 100%;"></div>	<p><b>Recipient</b></p> <div style="border: 1px solid black; height: 60px; width: 100%;"></div>	
	<b>DONOR</b>	<b>RECIPIENT</b>
<p><b>09. Neuromotor development:</b></p> <p>1 Normal <span style="margin-left: 100px;"><input type="radio"/> 1</span> <span style="margin-left: 100px;"><input type="radio"/> 1</span></p> <p>2 Delayed motor development <span style="margin-left: 100px;"><input type="radio"/> 2</span> <span style="margin-left: 100px;"><input type="radio"/> 2</span></p> <p>3 Abnormal motor development <span style="margin-left: 100px;"><input type="radio"/> 3</span> <span style="margin-left: 100px;"><input type="radio"/> 3</span></p> <p>4 Cerebral palsy <span style="margin-left: 100px;"><input type="radio"/> 4</span> <span style="margin-left: 100px;"><input type="radio"/> 4</span></p> <p><small>Definition of cerebral palsy: 'A non-progressive permanent impairment of voluntary movement of posture presumed to be due to damage of the developing brain before, during, or after birth, including hemiplegia. (ICD-10:G80)</small></p>		
<p><b>10. Bayley's scale for motor development:</b> Bayley N. Bayley scales of infant development. <i>The psychological Corporation Press, New York, 1969</i></p>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>
<p><b>11. Mental development (clinical impression):</b></p>	<p><input type="radio"/> Normal</p> <p><input type="radio"/> Abnormal</p>	<p><input type="radio"/> Normal</p> <p><input type="radio"/> Abnormal</p>

Study: **Observational study on TTS** - Surgeon:   
**Randomized Controlled Trial (RCT) on TTS**  
Underline or circle the applicable study

Patient:

## F98 Infant follow-up at 7-12 months (page 2)

**12. Specify abnormality:**

Please complete this field if the answer to the previous question is answered 'Abnormal'.

**Donor**

**Recipient**

**DONOR**

**RECIPIENT**

**13. Bayley's scale for mental development:**

Bayley N. Bayley scales of infant development.  
*The psychological Corporation Press, New York, 1969*

**14. Ophthalmologic examination:**

- Normal
- Abnormal

- Normal
- Abnormal

**15. Specify abnormality:**

Please complete this field if the answer to the previous question is answered 'Abnormal'.

**Donor**

**Recipient**

**DONOR**

**RECIPIENT**

**16. Hearing examination:**

- Normal
- Abnormal

- Normal
- Abnormal