TRAPIST - case record form

Twin Reversed Arterial Perfusion Intervention STudy

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Use black ballpoint pen to complete the CRF.

Enter the patient identifier in the header section of each form.

Required fields

Required fields are indicated by a * symbol next to the name.

Corrections

Do not delete or cover incorrectly entered data.

Please cross out the incorrect value and write the correction next to it. Date and initial each change.

Date/time formats

Dates should be specified in **day/month/year** format e.g. **13/04/2012**.

Times should be specified in **hour:minute** format in 24h clock e.g. **05:45**, **22:07**.

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Study completion

Withdrawal from follow-up visit

Withdrawal

Study entry visit

Timepoint: 0 days

Forms

Study entry

General information

Study entry

Enter the patient identifier and the date of entry to the study

Study entry

Identifier *

Date of study entry *

DD / MM / YYYY

General information

General information prior to randomisation

Patient's intials *

Patient's date of birth *

DD / MM / YYYY

Estimated due date *

DD / MM / YYYY

Randomisation visit

Timepoint: 0 days

Forms

Randomisation form

Randomisation form

Randomisation

Gestational age (GA) at inclusion *

Please tick one of the following options:

- ☐ 11 weeks and 6 days - 12 weeks and 6 days
- ☐ 13 weeks - 13 weeks and 6 days

Inclusion criteria

All answers must be YES

Does the patient expect a MCDA twin pregnancy complicated by TRAP? *

- ☐ Yes
- ☐ No

Is the GA between 11.6 weeks and 13.6 weeks? *

- ☐ Yes
- ☐ No

GA is determined by the CRL of the pump twin in spontaneous conceptions and by the date of insemination or embryonic age at replacement in pregnancies resulting from subfertility treatment

Can the acardiac twin be accessed safely for early intrafetal ablation? *

- ☐ Yes
- ☐ No

e.g. no superimposed bowel, placenta or fibroids, no hindrance by a retroverted uterus

Does the pump twin appear anatomically normal? *

- ☐ Yes
- ☐ No

Is the patient 18 years or more and is she able to consent? *

- ☐ Yes
- ☐ No

Did the patient provide written informed consent to participate in this RCT? *

- ☐ Yes
- ☐ No

Exclusion criteria

All answers must be NO

Is there a contraindication for an intrauterine intervention? *

- ☐ Yes
- ☐ No

e.g. due to a severe maternal medical condition, threatening miscarriage or major placenta praevia

Is there a spontaneous arrest of the reversed flow? *

- ☐ Yes
- ☐ No

Demographic details visit

Timepoint: 6 weeks

Forms

Demographic details

Demographic details

Demographic details

Parity *

Number (up to 2 digits)

Must be between 0 and 20

Mode of conception *

Please tick one of the following options:

- ☐ Spontaneous
- ☐ Ovulation induction
- ☐ IVF or ICSI

History of late miscarriage *

Please tick one of the following options:

- ☐ Yes
- ☐ No

History of late miscarriage between 14 and 24 weeks

History of preterm birth *

Please tick one of the following options:

- ☐ Yes
- ☐ No

History of preterm birth between 24.1 and 34 weeks

Patient's height *

cm

Number (up to 3 digits)

Must be between 100 and 250

Patient's weight *

kg

Number (to 1 decimal place)

Must be between 30 and 300

Weight at the time of inclusion

Patient's race/ethnicity *

Please tick one of the following options:

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Black or African American
- ☐ Hispanic or Latino
- ☐ White
- ☐ Other or Mixed

American Indian or Alaska native: A person with origins in any of the original peoples of North, Central and South America, and who maintains tribal affiliation
Asian: A person with origins in the Far East, Southeast Asia, or the Indian subcontinent, including Pakistan and Philippine Islands
Black or African American: A person with origins in any of the black racial groups in Africa
White: A person with origins in Europe, the Middle-East or North-Africa

Patient's education status *

Please tick one of the following options:

- ☐ Higher education
- ☐ No higher education

Higher education = minimum 2 years of additional training after high school

Social economic status of the family *

Please tick one of the following options:

- ☐ Upper middle class
- ☐ Middle class
- ☐ Lower middle class
- ☐ Skilled working class
- ☐ Working class
- ☐ Non working
- ☐ Student

Upper middle class = higher managerial, administrative or professional
Middle class = intermediate managerial, administrative or professional
Lower middle class = Supervisory or clerical and junior managerial, administrative or professional
Skilled working class = skilled manual workers
Working class = semi-skilled and unskilled manual workers
Non working = casual or lowest grade workers, pensioners and others who depend on the welfare state for their income
Student = not yet graduated

Smoking *

Please tick one of the following options:

- ☐ Yes
- ☐ No

Current smoking status

Chronic maternal disease *

Please tick one of the following options:

- ☐ Yes
- ☐ No

If chronic maternal disease, please specify

Intervention visit

Timepoint: 6 weeks

Forms

Operative details

Operative details

Operative details

Operative details

Date of surgery *

DD / MM / YYYY

Procedure technique *

Please tick one of the following options:

- ☐ Intrafetal coagulation
- ☐ Endoscopic laser coagulation (only allowed for late intervention)

Type of energy used *

Please tick one of the following options:

- ☐ laser
- ☐ RFA
- ☐ microwave
- ☐ other

If other, please specify:

Predominant placental position *

Please tick one of the following options:

- ☐ Anterior
- ☐ Posterior
- ☐ Lateral
- ☐ Fundal

Maximum diameter of entry instrument *

Please tick one of the following options:

- ☐ 20 G
- ☐ 19 G
- ☐ 18 G
- ☐ 17 G (only allowed for late intervention)
- ☐ 7 Fr (only allowed for late intervention)

Duration of procedure *

_____ minutes

Number (up to 3 digits)

Must be between 0 and 300

Total skin to skin time

Arrest of reversed flow *

Please tick one of the following options:

- ☐ Yes
- ☐ No

Intraoperative complications *

Please tick one of the following options:

- ☐ Yes
- ☐ No

If intraoperative complications, specify

e.g. septostomy, bleeding, amnionchorion dehiscence

Postoperative period visit

Timepoint: 8 weeks

Forms

Postoperative complications

Postoperative complications

within the first 2 weeks after the intervention

Maternal postoperative complications

If the answer is YES to any of the following items, report within 24 hours as a (potential) serious adverse event (SAE) - SAE forms are available on the study website www.monochorionictwins.org

Need for transfusion for postoperative hemorrhage *

Please tick one of the following options:

- ☐ Yes
- ☐ No

Placental abruption *

Please tick one of the following options:

- ☐ Yes
- ☐ No

Sepsis *

Please tick one of the following options:

- ☐ Yes
- ☐ No

Bowel perforation *

Please tick one of the following options:

- ☐ Yes
- ☐ No

Admission of the patient to ICU *

Please tick one of the following options:

- ☐ Yes
- ☐ No

If admission to ICU, please specify circumstances

Death of the patient *

Please tick one of the following options:

- ☐ Yes
- ☐ No

If maternal death, please specify circumstances

Pregnancy and delivery visit

Timepoint: 30 weeks

Forms

Pregnancy and delivery

Pregnancy and delivery

Pregnancy complications

From intervention until delivery

PPROM *

Please tick one of the following options:

☐ Yes

☐ No

PPROM is defined as spontaneous rupture of the membranes prior to 37 weeks and prior to the onset of contractions

If PPROM, please specify date

DD / MM / YYYY

IUFD *

Please tick one of the following options:

☐ Yes

☐ No

If IUFD, please specify date

DD / MM / YYYY

IUFD can be antepartum as well as intrapartum and can be spontaneous as well as iatrogenic due to feticide or TOP

If IUFD, please specify suspected cause of death

Especially if the result of feticide and TOP

Hospitalisation for preterm labour *

Please tick one of the following options:

☐ Yes

☐ No

Requiring hospitalisation for tocolysis and steroids

If hospitalisation for preterm labour, please specify number of days patient was admitted

_____ days

Number (up to 3 digits)

Must be between 0 and 180

Chorioamnionits as confirmed by pathology *

Please tick one of the following options:

☐ Yes

☐ No

Congenital malformations diagnosed between randomisation and delivery *

Please tick one of the following options:

☐ Yes

☐ No

If congenital malformations, please specify

Need for re-intervention *

Please tick one of the following options:

☐ Yes

☐ No

If re-intervention, please specify type of intervention

If re-intervention, please specify date

DD / MM / YYYY

Need for intrauterine transfusion (IUT) *

Please tick one of the following options:

☐ Yes

☐ No

If IUT, specify number of IUTs

Number (up to 2 digits)

Must be between 1 and 99

Delivery

Including miscarriage and TOP

Date of delivery *

DD / MM / YYYY

Mode of delivery *

Please tick one of the following options:

☐ Vaginal delivery

☐ Caesarean section

Onset of delivery *

Please tick one of the following options:

- ☐ Spontaneous
- ☐ Induced for maternal reasons
- ☐ Induced for fetal reasons

Please specify reason for induction

This also includes TOP

Neonatal outcome visit

Timepoint: 34 weeks

Forms

Neonatal details

Neonatal details

related to the first 28 days of life

Neonatal details

Is the pump twin liveborn? *

Please tick one of the following options:

- ☐ Yes
- ☐ No

Gender *

Please tick one of the following options:

- ☐ Male
- ☐ Female

Birthweight *

_____ grams

Number (up to 4 digits)

Must be between 10 and 6000

Congenital malformations first diagnosed or confirmed after delivery *

Please tick one of the following options:

- ☐ Yes
- ☐ No

If congenital malformations, please specify

Ischemic limb injury *

Please tick one of the following options:

☐ Yes

☐ No

Amniotic band injuries *

Please tick one of the following options:

☐ Yes

☐ No

Death within 28 days after birth

Please tick one of the following options:

☐ Yes

☐ No

If death in the neonatal period, please specify date

DD / MM / YYYY

Describe suspected cause of death

Severe cerebral injury

Please tick one of the following options:

☐ Yes

☐ No

Defined as PVL grade 2 or higher, IVH grade 3 or higher, ventricular dilatation greater than the 97th centile, porencephalic or parenchymal cysts or other severe cerebral lesions associated with adverse neurological outcome

If severe cerebral injury, please specify

Chronic lung disease

Please tick one of the following options:

☐ Yes

☐ No

Chronic lung disease is defined as oxygen dependency at 36 weeks GA or at discharge (whichever comes first) for infants born prior to 32 weeks OR oxygen dependency at age more than 28 days or at discharge (whichever comes first) for infants born after 32 weeks

Patent ductus arteriosus requiring treatment

Please tick one of the following options:

☐ Yes

☐ No

Answer yes, only if requiring either medical (NSAID) or surgical treatment

Necrotizing enterocolitis

Please tick one of the following options:

☐ Yes

☐ No

Answer yes, only if Bell stage 2 or higher

- Stage 1. Suspected NEC: gastric residuals, abdominal distension, occult or gross blood in stool, x-ray normal to mild distension, temperature instability, apnea, bradycardia
- Stage 2. Definite NEC: mild to moderate systemic illness, absent bowel sounds, abdominal tenderness, pneumatosis intestinalis or portal venous gas, metabolic acidosis, ↓ platelets
- Stage 3. Advanced NEC: severely ill, marked distension, signs of peritonitis, hypotension, metabolic & respiratory acidosis, DIC, pneumoperitoneum if bowel perforation present

Retinopathy of prematurity

Please tick one of the following options:

☐ Yes

☐ No

Answer yes, only if stage 3 or higher

- Stage 1 Demarcation line
- Stage 2 Intraretinal ridge
- Stage 3 Ridge with extraretinal fibrovascular proliferation
- Stage 4 Subtotal retinal detachment
- Stage 5 Total retinal detachment

Extra comment

Long term follow-up visit

Timepoint: 134 weeks

Forms

Long term infant outcome

Long term infant outcome

General long term outcome

Child alive

Please tick one of the following options:

☐ Yes

☐ No

If infant death, please specify date

DD / MM / YYYY

If infant death, please specify circumstances

Cerebral palsy

Please tick one of the following options:

☐ Yes

☐ No

Type of cerebral palsy, if present

Please tick one of the following options:

☐ Diplegia

☐ Hemiplegia

☐ Quadriplegia

☐ Dyskinetic or mixed

Bilateral blindness

Please tick one of the following options:

☐ Yes

☐ No

Deafness requiring amplification

Please tick one of the following options:

☐ Yes

☐ No

ASQ at the corrected age of 2 years

ASQ score performed

Please tick one of the following options:

☐ Yes

☐ No

Date of ASQ assessment

DD / MM / YYYY

Score for communication

Number (up to 3 digits)

Must be between 0 and 200

Score for gross motor skills

Number (up to 3 digits)

Must be between 0 and 200

Score for fine motor skills

Number (up to 3 digits)

Must be between 0 and 200

Score for problem solving

Number (up to 3 digits)

Must be between 0 and 200

Score for personal and social skills

Number (up to 3 digits)

Must be between 0 and 200

Bayley III at the corrected age of 2 years

Bayley III score available

Please tick one of the following options:

☐ Yes

☐ No

Date of Bayley III assessment

DD / MM / YYYY

Score for cognitive development

Number (up to 3 digits)

Must be between 0 and 200

Score for language development

Number (up to 3 digits)

Must be between 0 and 200

Score for motor development

Number (up to 3 digits)

Must be between 0 and 200

Score for social development

Number (up to 3 digits)

Must be between 0 and 200

Score for adaptive development

Number (up to 3 digits)

Must be between 0 and 200

Composite score

Number (up to 3 digits)

Must be between 0 and 200

Study completion form visit

Timepoint: 140 weeks

Forms

Study completion

Study completion

Study completion

Study completion

Has the patient completed the study? *

Please tick one of the following options:

☐ Yes

☐ No

If no, specify reason

e.g. loss-to-follow up, serious adverse event, withdrawal of consent

Please specify the date of the latest follow-up? *

DD / MM / YYYY

If the patient completed the study, the date corresponds to the 2 yr assessment
If the patient did not complete the study, the date corresponds to the latest follow-up

Has there been a breach of protocol? *

Please tick one of the following options:

☐ Yes

☐ No

If yes, please specify:

e.g. patient was randomized to the early group but treated after 14 weeks GA

Withdrawal from follow-up visit

Timepoint: At any time

Forms

Withdrawal

Withdrawal

Enter the date of withdrawal from follow-up. CRF data will not be collected on this patient after this date.

Study withdrawal

Date of withdrawal from follow-up *

DD / MM / YYYY

Reason for withdrawal