The TAPS Trial - Laser Surgery for Twin Anemia Polycythemia Sequence

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26505

Source
Nationaal Trial Register

Brief title
The TAPS Trial

Health condition

Twin Anemia Polycythemia Sequence (Tweeling Anemie Polycythemie Sequentie)
Monochorionic Twins (Monochoriale tweelingen)
Feto-fetal transfusion syndrome (foeto-foetaal transfusiesyndroom)
Fetoscopic Laser Surgery (Foetoscopische Laserchirurgie)
Twin-to-Twin Transfusion Syndrome (Tweelingtransfusiesyndroom)

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: No funding.

Intervention

Outcome measures

Primary outcome

The primary outcome is gestational age at birth.

Secondary outcome

Secondary outcomes include: perinatal mortality or severe neonatal morbidity, hematological complication, procedure related complications and long-term neurodevelopmental outcome at 2 years.

Study description

Background summary

Monochorionic twins share one placenta and are connected to each other via vascular anastomoses at the placental surface, allowing the blood to transfer bi-directionally between the two fetuses. Unbalanced inter-twin blood transfusion can result in twin anemia-polycythemia sequence (TAPS). Management options include: fetoscopic laser surgery, intrauterine blood transfusion (IUT) with or without partial exchange transfusion (PET), preterm delivery, selective feticide and expectant management. The optimal treatment for TAPS is not clear. Fetoscopic laser surgery is the only causative treatment option, but data on the feasibility of this procedure are mainly based on case reports and small cohort studies. A large randomized controlled trial is needed to evaluate the possible beneficial effect of fetoscopic laser surgery and to determine the optimal treatment option for TAPS.

Objective: The aim of this trial is to investigate whether fetoscopic laser surgery improves the outcome for TAPS twins as compared to the control group (standard care consisting of expectant management, IUT, preterm delivery). The hypothesis is that fetoscopic laser therapy will improve neonatal outcome by prolonging pregnancy.

Study design: International multi-centered open-label randomized controlled trial to assess whether fetoscopic laser surgery (experimental group) improves the outcome of TAPS twins compared to standard care (control group).

Study population: Monochorionic twin pregnancies with TAPS stage ≥ 2 (spontaneous or post-laser) diagnosed between 20 and 28 weeks of gestation.

Intervention: In the experimental group fetoscopic laser surgery is performed, whereas the control group is treated with standard care (expectant management, IUT (with PET), selective feticide and/or preterm delivery, depending on the opinion of the fetal surgeon).

Main study endpoints: The primary outcome is gestational age at birth. Secondary outcomes include: perinatal mortality or severe neonatal morbidity, hematological complication, procedure related complications and long-term neurodevelopmental outcome at 2 years.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Fetoscopic laser surgery is performed for several decades now and is considered the golden standard for another feto-fetal transfusion syndrome, namely twin-twin transfusion syndrome. Although fetoscopic laser surgery is associated with a higher risk on several complications (including single or double intrauterine fetal demise, iatrogenic monoamniocity, amnion dehiscention, intra-uterine infection and preterm premature rupture of the membranes), the natural course of TAPS on itself is characterized by high rates of morbidity and mortality as well. The additional risk of fetoscopic laser treatment on top of the risks that are already associated with the natural course of TAPS is therefore estimated as low. The benefit of participating is that TAPS twins allocated to the fetoscopic laser surgery group might be born at a higher gestational age and therefore have a better neonatal outcome.

Study objective

The hypothesis is that fetoscopic laser therapy will improve neonatal outcome in TAPS twins by prolonging pregnancy.

Study design

Diagnosis

Birth

Birth - 28 days after birth

Corrected age of 2 years

Intervention

In the experimental group fetoscopic laser surgery is performed, whereas the control group is treated with standard care (expectant management, IUT (with PET), selective feticide and/or preterm delivery, depending on the opinion of the fetal surgeon).

Contacts

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Eligibility criteria

Inclusion criteria

• Monochorionic twin pregnancy complicated by either spontaneous or post-laser TAPS, stage ≥ 2, diagnosed between 20+0 and till 28+0 weeks of gestation

• Women aged 18 years or more, who are able to consent.

Exclusion criteria

• TAPS stage 1

• TAPS stage≥ 2, diagnosed within 1 week after laser surgery for TTTS*

• Triplet pregnancies, or higher order multiple pregnancies

• TAPS cases that already underwent an intrauterine treatment (with the exception of laser surgery for TTTS in post-laser TAPS cases)

• Congenital abnormalities (including severe cerebral injury) in one or both twins

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-07-2018
Enrollment:	44
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 46380
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6879
NTR-old	NTR7057
CCMO	NL64427.000.18
OMON	NL-OMON46380

Study results