The TAPS Trial;Fetoscopic Laser Surgery for Twin Anemia Polycythemia Sequence: a multicenter open label randomized controlled trial

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Foetal complications
Study type	Interventional

Summary

ID

NL-OMON46380

Source
ToetsingOnline

Brief title
The TAPS Trial

Condition

- Foetal complications

Synonym
Er is geen lekenterm voor deze aandoening, TAPS

Research involving
Human

Sponsors and support

Primary sponsor: Verloskunde

Source(s) of monetary or material Support: Studie heeft geen financiering.

Intervention

Keyword: Fetoscopic laser surgery, Monochorionic Twins, Twin Anemia Polycythemia Sequence

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.

Study 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).

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).

Study burden and risks

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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Monochorionic Twin Pregnancy diagnosed with Twin Anemia Polycythemia Sequence (stage 2 or higher), with a gestational age 20-28

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
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-04-2019
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	18-12-2018
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	15-12-2020
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26505
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL64427.000.18
OMON	NL-OMON26505