Solomon study

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23535

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Twin-to-twin transfusion syndrome
Twin anemia-polycythemia sequence
Fetoscopic laser surgery

Sponsors and support

Primary sponsor: NA
Source(s) of monetary or material Support: -

Intervention

Outcome measures

Primary outcome

Primary outcome measure will be the prevalence of TAPS or recurrence of TTTS.

4-7-2013: An adjustment to the primary outcome and sample size calculation was made after the start of recruitment and was approved by the medical ethics committee (P07.261). The initial primary outcome was reduction of TAPS and recurrent TTTS and sample size was based

on a reduction of 15% (20% in the Solomon group versus 5% in the Selective group). Secondary outcomes were perinatal mortality and neonatal morbidity. Since it was of high importance to show that the use of the new treatment modality would not have a negative effect on perinatal mortality and neonatal morbidity, we therefore included perinatal mortality and severe neonatal morbidity in the primary outcome. The expected reduction of the composite outcome of 15%, with 45% in the Solomon group and 60% in the selective group, increased the sample size from 184 to 274 patients.

Secondary outcome

Secondary outcomes include residual anastomoses on placental injection, perinatal mortality and neonatal morbidity.

Study description

Background summary

As shown in a recent randomized trial, the best available treatment for twin-to-twin transfusion syndrome (TTTS) to date is fetoscopic laser surgery. The aim of fetoscopic laser treatment is to interrupt the inter-twin circulation through coagulation of the vascular anastomoses on the placental surface.
Several studies have shown that laser treatment for TTTS is not always effective and failure can lead to severe complications. Up to 33% of placentas treated with laser may still have residual anastomoses. These residual anastomoses can lead to several hematologic complications, including the twin anemia-polycythemia sequence (TAPS).
A possible solution to the problem would be to adopt an alternative laser surgery technique, in which not only the anastomoses but the entire vascular equator is coagulated. The main goal of this technique is to reduce the incidence of small, residual anastomoses.
The aim of this multicenter randomized controlled trial is to compare the new laser-technique in which both placenta shares are separated by coagulation of the entire vascular equator (hence the term "Solomon") to the currently most often used selective laser technique where only the visible vascular anastomoses are coagulated.

Study objective

To determine whether the ‘Solomon laser-technique’, in which the entire vascular equator is coagulated, reduces the prevalence of TAPS or recurrence of TTTS when compared to the ‘selective laser-technique’, in which only the identifiable vascular anastomoses are coagulated.

Study design

Follow-up of TTTS survivors will be 2 year.

Intervention

‘Solomon technique’: after identification and coagulation of each individual anastomosis, the complete vascular equator is coagulated from one placental margin to the other. Compared to the ‘Selective technique’: The vascular anastomoses are first identified and subsequently coagulated one by one.

Contacts

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Eligibility criteria

Inclusion criteria

1. All TTTS pregnancies eligible for laser surgery up to 26 weeks’ gestation.

Exclusion criteria

1. Triplet pregnancies

2. Language problems for informed consent.

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):	15-03-2008
Enrollment:	184
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	04-03-2008
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL1200
NTR-old	NTR1245
Other	METC LUMC : P07.261
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A