Solomon study

Gepubliceerd: 04-03-2008 Laatst bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23535

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

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

Ondersteuning

Primaire sponsor: NA
Overige ondersteuning: -

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Follow-up of TTTS survivors will be 2 year.

Onderzoeksproduct en/of interventie

‘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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Triplet pregnancies

2. Language problems for informed consent.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	15-03-2008
Aantal proefpersonen:	184
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	04-03-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A