Intrauterine infection in TTTS after laser therapy: incidence, risk factors and perinatal outcome

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To evaluate the incidence, risk factors and perinatal morbidity and mortality due to CA after TTTS treated with fetoscopic laser surgery.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON39019

Source
ToetsingOnline

Brief title
CA-TTS study

Condition

- Hepatobiliary neoplasms malignant and unspecified
- Placental, amniotic and cavity disorders (excl haemorrhages)

Synonym
amnion, intrauterine infection. Infection of placenta, neonate

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: D. Zhao wordt gesubsidieerd door China Scholarship Council (CSC)

Intervention

Keyword: chorioamnionitis, chronic villitis, funisitis, intrauterine infection, twin-to-twin transfusion syndrome (TTTS)

Outcome measures

Primary outcome

incidence of intrauterine infection (chorioamnionitis and/or funisitis) in TTTS

after fetoscopic laser surgery

Secondary outcome

1. risk factors of IUI in TTTS after fetoscopic laser surgery

2. disparities of IUI between donor and recipient twin

3. relationship of IUI and neonatal outcomes

Study description

Background summary

MC twin pregnancies are regarded as high risk pregnancies primarily due to the increased risk of TTTS (10%). The best available treatment for TTTS is fetoscopic laser coagulation of the placental vascular anastomoses. Nevertheless, TTTS survivors after laser surgery are at increased risk of cerebral injury and impaired long-term neurodevelopmental outcome. TTTS pregnancies treated with laser have an increased risk of iatrogenic PPROM (up to 78-93%), which may be attributed to the creation of a hole in the membranes after introduction of the fetoscope in the amniotic sac of the recipient twin. This iatrogenic hole in the membranes may directly expose the recipient twin to microbial invasion with or without maternal manifestation. PPROM is known to be associated with increased risk of premature delivery and adverse perinatal outcome, mainly due to intrauterine infection (IUI). Recent reports have shown that chorioamnionitis (CA) is associated with neonatal cerebral injury and adverse long-term neurodevelopmental outcome. Not much is known on the incidence, risk factors and related perinatal outcome. Only few small studies have evaluated the occurrence of clinical or histological CA in TTTS treated with laser. Larger, well-designed studies are urgently required to determine the incidence and risk factors of CA in TTTS treated by laser.

Study objective

To evaluate the incidence, risk factors and perinatal morbidity and mortality due to CA after TTTS treated with fetoscopic laser surgery.

Study design

A case control prospective study.

Study burden and risks

no associated risk with participation

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

All TTTS cases treated with fetoscopic laser surgery at our center are eligible for our study. All monochorionic twins without TTTS delivered at our center will be included in the control group.

Exclusion criteria

Higher order pregnancies will be excluded from the study.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-03-2013
Enrollment:	122
Type:	Actual

Ethics review

Approved WMO

Date:	12-03-2013
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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
CCMO	NL43297.058.13