

Fibronectin as predictor of preterm labour in monochorionic twins treated with fetoscopic laser surgery

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To determine whether fFN can detect preterm delivery in monochorionic twins treated for TTTS.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Maternal complications of pregnancy
Study type	Observational invasive

Summary

ID

NL-OMON32520

Source

ToetsingOnline

Brief title

Fibronectin in treated TTTS patients

Condition

- Maternal complications of pregnancy

Synonym

partus prematures bij het tweelingtransfusie syndroom(TTS), vroeggeboorte bij TTS

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: fetoscopic laser surgery, fibronectin, preterm labour, twin to twin transfusion syndrome

Outcome measures

Primary outcome

Delivery within 7 days. Gestational age <34 weeks and < 37weeks.

Secondary outcome

Neonatal mortality and morbidity.

Study description

Background summary

Twin to twin transfusion syndrome (TTTS) is a condition in which blood from one twin (the donor) is transfused into the other twin (the recipient) via blood vessels in their common placenta. It occurs in 15% of identical twins that share a placenta (about two percent of all twin pregnancies). It has potentially serious and life threatening effects upon both twins. Normally, identical monochorionic twins have blood vessels that connect to each other on the surface of the placenta. Blood can flow from one twin to the other but this flow is balanced in both directions. TTTS occurs when there is a disturbance to this balance and there is a "net" flow of blood from the donor to the recipient twin. The donor twin decreases the amount of amniotic fluid and the recipient twin gets too much amniotic fluid and often gets heart problems. The best available treatment for TTS is fetoscopic laser surgery. The aim of the fetoscopic laser treatment is to interrupt the inter-twin circulation through coagulation of the vascular anastomoses on the placental surface. The fetoscope is 3mm thick and has to pass the uterus wall and the membranes to reach the placental surface. The risk of rupture of membranes after laser treatment is 10%. It's very important to predict and detect preterm labour in an early stage. Fetal fibronectine proved to be a good marker for preterm labour in singletons but is never tested in monochorionic twins treated for TTTS

Study objective

To determine whether fFN can detect preterm delivery in monochorionic twins

treated for TTTS.

Study design

Prospective trial.

Time schedule:

Before procedure:

- Fibronectin swab
- Vaginal swab (culture)
- Cervixlength measurement
- Bloodsample (7ml)

During procedure, 15ml amniotic fluid (which will be drained to reduce the polyhydramnios):

- 5 ml PCR
- 5 ml Luminex (cytokine assay)
- 5 ml culture

1 day after procedure:

- Fibronectin swab

After delivery:

- A part of the amnion and umbilical cord will be send to the department of pathology to investigate whether there are signs of chorioamnionitis and/or funiculitis

Study burden and risks

Treatment and follow-up of all TTTS patients are according to standardized care. There will be two extra examinations, before and one day after treatment.

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 monochorionic twin pregnancies complicated with TTTS requiring fetoscopic laser treatment

Exclusion criteria

Gebroken vliezen, >3 cm ontsluiting, cystitis of eerdere opname/overplaatsing in verband met dreigende partus prematurus.

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL
Recruitment status: Will not start
Start date (anticipated): 01-11-2009
Enrollment: 50
Type: Anticipated

Ethics review

Approved WMO
Date: 20-01-2010
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	NL30059.058.09