Early versus late intervention for twin reversed arterial perfusion sequence: an open-label randomized controlled trial *TRAPIST*: TRAP Intervention STudy

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To assess if early intervention (12.0-14.0 weeks) (study group) improves the outcome of TRAP sequence as compared to late intervention (16-18 weeks) (control group).

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

Summary

ID

NL-OMON43488

Source
ToetsingOnline

Brief title
See above

Condition

- Foetal complications

Synonym
TRAP acardiacus / alive fetus with no heart - TRAP pump twin/ twin giving blood to demised co twin

Research involving
Fetus in utero

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

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

Intervention

Keyword: Intervention, MC twin pregnancy, Survival pump twin, TRAP

Outcome measures

Primary outcome

Pump twin neonatal survival and birth at or after 34.0 weeks.

Secondary outcome

Need for re-intervention, maternal morbidity, gestational age at birth,

neonatal outcome, 2-year neurodevelopmental outcome

Study description

Background summary

Twin reversed arterial perfusion sequence (TRAP) is a rare anomaly unique to monochorionic twin pregnancies, with an estimated prevalence of 1 in 35 000 pregnancies but with a mortality of more than 50% for the healthy pump twin1. Monochorionic twins are identical and share a single placenta with vascular anastomoses that connect the two fetal circulations. TRAP is a complication of this shared circulation and occurs if one of the twins dies in early pregnancy. In TRAP, blood flows from a structurally normal pump twin in a reverse direction towards its demised co-twin, which becomes a true parasite without cardiac activity from its own, hence also called the acardiac twin. TRAP is nowadays diagnosed already at the 12 weeks ultrasound scan and is characterized by a monochorionic twin pregnancy with one structurally normal and one grossly abnormal twin

If the pump twin survives to 16 weeks and is treated thereafter, approximately 80% will survive8. However, a major disadvantage of delaying the intervention until after 16 weeks* gestation is the high mortality of the pump twin (up to 33%) between the diagnosis at 12 weeks and the planned intervention at 16 weeks9. These early demises are entirely unpredictable9. As such, the survival rate for TRAP diagnosed at 12 weeks and treated after 16 weeks is estimated to only about 50%8 9. Also, a recent meta-analysis demonstrated an inverse relationship between gestational age at treatment and gestational age at birth, suggesting that an earlier intervention may decrease the risk of very preterm

birth. An intervention at 12-14 weeks may thus prevent the early deaths and reduce the risk of very preterm birth, but might also increase the risk the miscarriage because of premature rupture of the membranes.

Study objective

To assess if early intervention (12.0-14.0 weeks) (study group) improves the outcome of TRAP sequence as compared to late intervention (16-18 weeks) (control group).

Study design

International multicentre open label randomized controled trial

Intervention

Early group; Intrafetal coagulation to stop reversed flow.
Late group; either Intrafetal coagulation or fetoscopic laser coagulation of the cord and / or anastomoses. to stop reverse flow.

Study burden and risks

Burden is not higher/more as compared to standard of care. Only difference might be earlier intervention due to randomisation outcome.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

MCDA twin pregnancy
Complicated by TRAP sequency diagnosed between 11+6 and 13+6 weeks AD
Anatomically normal pump twin
Age > 18
Informed consent

Exclusion criteria

Contraindication for an intervention due to a severe maternal medical condition or threatening miscarriage
*Inaccessibility of the acardiac twin due to a retroverted uterus, severe maternal obesity, uterine fibroids, bowel or placental superposition
*A major anomaly in the pump twin, requiring surgery or leading to infant death or severe handicap
*Spontaneous arrest of the reverse flow and/or pump twin demise at diagnosis

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):	16-08-2016
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	19-05-2016
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT02621645
CCMO	NL56530.000.16