DRIGITAT: Doppler Ratio In fetal Growth restriction Intervention Trial At (near) Term

No registrations found.

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

Summary

ID

NL-OMON29445

Source
NTR

Brief title
DRIGITAT

Health condition

Fetal growth restrion, foetale groeirestrictie

Sponsors and support

Primary sponsor: Academisch Medische Centrum (AMC) - Amsterdam
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

7-point average difference MDI/PDI Bayley-III at 2 years

Secondary outcome

Composite outcome of neonatal morbidity appropriate for late preterm gestations, perinatal mortality, mode of delivery, maternal quality of life, costs.

Study description

Background summary

NA

Study objective

Implementation of UCR as diagnostic marker for fetal compromise in SGA improves long-term neurodevelopmental outcome by identifying fetuses with fetal growth restriction (FGR) within the SGA group who will benefit from earlier delivery, improving health outcomes and saving healthcare resources.

Study design

Primary:

- 7-point average difference MDI/PDI Bayley-III (timepoint: 2 years)

Secondary

- Registry of neonatal morbidity, perinatal mortality, mode of delivery (timepoint: perinatal/neonatal period)

Intervention

Delivery at 36 weeks when UCR is abnormal and fetal growth is mildly abnormal (EFW/FAC p3-p10) and delivery at 34 weeks when UCR is abnormal and fetal growth is severely abnormal (EFW/FAC below p3).

Contacts

Public
AMC
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The Netherlands
-
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Eligibility criteria

Inclusion criteria

o Inclusion criteria cohort:
- Singleton pregnancy
- Identified SGA (estimated fetal weight or fetal abdominal circumference below 10th percentile)
- 32+0 – 37+0 weeks of gestation

o Inclusion in RCT (in addition to the above-mentioned criteria)
- Abnormal UmbilicoCerebral Ratio (UCR): ≥0.8 on at least 2 occasions with an interval of at least one day
AND
- EFW and/or FAC

Exclusion criteria

- Maternal age <18 years

- Multiple pregancies

- Suspicion of congenital abnormalities

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	29-12-2017
Enrollment:	185
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	14-08-2017
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	NL6475
NTR-old	NTR6663

Register	ID
Other	Projectnumber ZonMw : 843002825

Study results