

The Disproportionate Intrauterine Growth Intervention Trial At Term (DIGITAT), long-term follow up.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24995

Source

Nationaal Trial Register

Brief title

DIGITAT-FU

Health condition

fetal growth restriction

Sponsors and support

Primary sponsor: ZonMW, UMCG, University of Amsterdam

Source(s) of monetary or material Support: ZOnMW, UMCG, University of Amsterdam, location AMC

Intervention

Outcome measures

Primary outcome

neurodevelopmental, behavioral abnormalities in childhood

Secondary outcome

maternal and childhood adverse health outcomes (like hypertensive disease and allergic constitution)

Study description

Background summary

We will conduct a follow up of the DIGITAT, a multi-center randomized intervention trial that investigated the role of induction of labour in case of (near) term fetal growth restriction.

Study objective

In the long term (neurodevelopment, behavioral) follow up we will see differences in the outcome of children who were born earlier after induction of labour and the children by whom labour was awaited for.

Study design

MEC application planned, mono-center follow up

Intervention

none in the follow up

Contacts

Public

UMCG

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Scientific

UMCG

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Eligibility criteria

Inclusion criteria

study participants of the original DIGITAT trial

Exclusion criteria

no informed consent

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	16-04-2019
Enrollment:	1102
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:

Not applicable

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	NL7599
Other	MEC UMCG : ABR 69255

Study results