Disproportionate Intrauterine Growth Intervention Trial At Term (DIGITAT): long-term follow-up

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- To investigate the long-term outcome of the intervention strategy for FGR (induction of labour) that is worldwide applied after the original DIGITAT study, in relation to induction of labour versus expectant management.- To investigate...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON47986

Source
ToetsingOnline

Brief title
DIGITAT: long-term follow-up

Condition

- Other condition
- Mental impairment disorders
- Developmental disorders NEC

Synonym
Fetal growth restriction, intrauterine growth retardation, placental insufficiency, small for gestational age

Health condition

antropometrie en algemene gezondheid

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,zonMW

Intervention

Keyword: Fetal growth restriction, Long-term follow-up, Maternal ouctomes, Neurocognitive behaviour and development

Outcome measures

Primary outcome

Long-term (neuro)developmental and behavioral outcome of pregnancies

complicated by fetal growth restriction at term in relation to induction of

labor or an expectant management.

Secondary outcome

Development of hypertensive disorders and general health of mothers and the

children.

Allergic constitution of the children.

Study description

Background summary

This study is a follow-up study of the Disproportionate Intrauterine Growth Intervention Trial at Term (DIGITAT), a prospective multicentre randomised study performed between 2004 and 2008. The aim of this study was to investigate whether the induction policy in pregnancies complicated with growth restriction between 36 and 41 weeks can influence outcome. A total of 650 women were randomised between induction and expectant monitoring. 452 Women refused randomisation but consented with the use of their medical data. Demographic data, data from the medical records of the mothers, data concerning the pregnancy and labour and neonatal outcome were collected. All data were coded

and stored in a central digital database and in digital databases of all participating centers respectively.

Parents of 2-year-old children included in the Disproportionate Intrauterine Growth Intervention Trial at Term (DIGITAT) answered the Ages and Stages Questionnaire (ASQ) and Child Behavior Checklist (CBCL). Parents of 291 children responded. Data from the paper questionnaires were collected in the digital DIGITAT database.

No data of long-term follow-up studies of randomized intervention trials for the common problem of FGR are published or currently undertaken. Therefore we aim to perform this important follow-up study at 10-14 years to investigate whether in the long term the worldwide early induction strategy that was implemented after DIGITAT is indeed the optimal strategy. This important follow-up study will guide pregnancy management for FGR.

Study objective

- To investigate the long-term outcome of the intervention strategy for FGR (induction of labour) that is worldwide applied after the original DIGITAT study, in relation to induction of labour versus expectant management.
- To investigate neurocognitive behaviour and development and the allergic constitution of children, in relation to induction of labor or an expectant management.

Study design

We will conduct a mono-center follow-up study of the original (multi-center) randomized controlled trial: DIGITAT. Parents will be contacted to participate in a follow-up of their children at 10 to 14 years of age. Both patients who were randomised in the DIGITAT (n=650) and patients who refused randomisation but consented with the use of their medical data (n=452) will be contacted. Patients will initially be approached by their local center with a brief summary of the follow-up study. If they want to participate or would like to receive additional information, the further course of this follow-up study will be coordinated from the UMCG. The questionnaires will be distributed, collected and analyses by the researchteam in the UMCG.
We will use digital questionnaires to collect data on neuro-cognitive development and behaviour data on allergic constitution of the children. General medical data of the mothers and children will be collected as well.

Study burden and risks

The only burden is the time needed to fill in the extensive questionnaires: 60-75 minutes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Patient who participated to randomisation or agreed with follow-up only in the original DIGITAT trial.

Exclusion criteria

Uncompleted questionnaires.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	1102
Type:	Anticipated

Ethics review

Approved WMO

Date:	30-04-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date:	26-06-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL69255.042.19