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Disproportionate Intrauterine Growth Intervention Trial At Term (DIGITAT)

Submission date	Recruitment status	[_] Prospectively registered
20/12/2005	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/12/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/05/2014	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.studies-obsgyn.nl/digitat/index.asp

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
DIGITAT

Study objectives
Early induction of labour being an effective intervention e.g. for the prevention of neonatal neurologic morbidity for foetus with established disproportionate intrauterine growth retardation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Multicentre randomised active-controlled parallel-group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Intrauterine Growth Failure

Interventions
Women will be randomly allocated to induction of delivery (intervention group) or expectant monitoring group (expectant group).

Foetal condition will be assessed using foetal heart rate pattern, sonographic measurement of amniotic fluid index, and Doppler measurement of the a. umbilicalis and a. cerebri media. If women are allocated to intervention, labour will be induced within 48 hours after randomisation. The method of induction will be at the obstetrician's discretion. Cervical ripening with prostaglandins, osmotic cervical dilatation or digital sweeping of the membranes is optional.

The use and timing of amionotomy and the timing and use of oxytocine regime (if used) will all follow local practice. Participants allocated to this group will not have labour induced unless the foetal condition or maternal condition requires a clear indication for this develops. They will be observed according to local practice until labour starts spontaneously. Foetal monitoring will be according to local practice. However, the minimal monitoring will include a weekly measurement of the umbilical artery Doppler waveform.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Under the condition of equal short-term neonatal outcome, the primary outcome will be the number of obstetrical interventions.

Neonatal outcome:
1. Umbilical cord pH less than 7.10
2. Base Excess less than -10
3. Apgar at 5 minutes less than 7
4. Neonatal admittance to Neonatal Intensive Care Unit (NICU)

Secondary outcome measures
1. Costs
2. Assessment of children later in life; postal enquiries as the Child Behavior Checklist (CBCL) and Ages and Stages Questionnaire (ASQ) will be used

Overall study start date
01/04/2005

Completion date
01/04/2008

Eligibility

Key inclusion criteria
1. Women with a presumed diagnosis of growth failure greater than 36 completed weeks
2. Women are identified initially by clinical assessment of foetal growth between 35 and 39 weeks. After identification, patients will be referred for foetal biometry, a non-stress test and Doppler ultrasound of the umbilical artery and the a. cerebri media
3. Patients in whom the diagnosis of growth failure greater than 36 is confirmed, and in whom the obstetrician is uncertain whether delivery is indicated or not are eligible for the study

4. The final entry criteria are an accurate ultrasound dating scan before 20 weeks and clinical suspicion of failure to thrive in-utero after 36 completed weeks or later, while the clinician is uncertain whether to induce or to await spontaneous delivery

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
600

Key exclusion criteria
1. Multiple pregnancy
2. Obstetrical history with caesarean section
3. Breech
4. Inaccurate dating of gestational age
5. Suspected congenital malformation
6. Foetal distress needing delivery

Date of first enrolment
01/04/2005

Date of final enrolment
01/04/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Leiden University Medical Centre
Leiden
Netherlands
2300 RC

Sponsor information

Organisation
Leiden University Medical Centre (LUMC) (Netherlands)

Sponsor details
Albinusdreef 2
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Sponsor type
University/education

Website
http://www.lumc.nl/

ROR
https://ror.org/027bh9e22

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organization for Health Research and Development (ZonMw) (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol to compare methods of validation:	04/07/2007		Yes	No
Protocol article	protocol results	10/07/2007		Yes	No

Results article		21/12/2010	Yes	No
Results article	economic analysis results	01/10/2013	Yes	No
Other publications	secondary analysis	01/01/2014	Yes	No