

Disproportionate Intrauterine Growth Intervention Trial At Term (DIGITAT)

Submission date 20/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/05/2014	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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)

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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)

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

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?
Results article	results	21/12/2010		Yes	No
Results article	economic analysis results	01/10/2013		Yes	No
Protocol article	protocol to compare methods of validation:	04/07/2007		Yes	No
Protocol article	protocol	10/07/2007		Yes	No
Other publications	secondary analysis	01/01/2014		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes