IRIS study - The IUGR Risk Selection Study.

No registrations found.

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

Summary

ID

NL-OMON23334

Source
NTR

Brief title
IRIS - IUGR RIsk Selection

Health condition

Perinatal death
Severe perinatal morbidity
IUGR - Intra Uterine Growth Restriction
SGA - Small for Gestational Age

Sponsors and support

Primary sponsor: VU University Medical Center Amsterdam
Source(s) of monetary or material Support: ZonMw - Netherlands Organisation for Health Research and Development

Intervention

Outcome measures

Primary outcome

The clinical primary outcome is a dichotomous composite measure ‘severe adverse perinatal

outcome’ up to 7 days after birth, including: perinatal death; Apgar score below 4 at 5 minutes after birth; impaired consciousness; asphyxia; neonatal seizures; need for assisted ventilation for more than 24 hours; septicaemia; meningitis; bronchopulmonary dysplasia; intraventricular haemorrhage; cystic periventricular leukomalacia; or necrotizing enterocolitis.
Also direct and indirect costs are primary outcomes.

Secondary outcome

COMPOSITE secondary outcomes
1. Spontaneous vaginal birth without intervention, i.e. a birth without any of the following:
- induction of labour other than amniotomy
- vacuum/ forceps
- caesarean section
- augmentation of labour
- pharmacological pain relief: epidural anaesthesia or use of opioids
2. Maternal morbidity, defined as the presence of one or more of the following:
- maternal death within 42 days after giving birth
- hypertension
- pre-eclampsia
- postpartum haemorrhage
- third or fourth degree perineal trauma

SINGULAR secondary outcomes:
- elements of composite primary outcome
- elements of the two composite secondary outcomes
- birth weight
- gestational age at birth
- neonatal mortality and severe morbidity between 7th and 28th day after birth
- detection of congenital abnormalities
- home and hospital birth in primary care
- non-cephalic presentations (when labour started) in primary care
- general quality of life - EQ-5D-5L
- pregnancy specific anxiety - PRAQ
- depression - EPDS
- maternal-fetal attachment - MAAS
- client satisfaction - subscale of PCQ

Study description

Background summary

BACKGROUND: Of all babies that die after 25 or more weeks gestation, 40% are small-for-gestational-age (SGA). In the Netherlands third trimester ultrasound (US) screening is

increasingly being used to monitor foetal growth even though evidence on its effectiveness or cost-effectiveness is lacking. The proposed study fulfils the urgent need to evaluate the value of third trimester US for monitoring foetal growth among low risk women in primary care. If shown to be effective, routine third trimester US will contribute to reducing the national perinatal mortality and severe morbidity rate.

DESIGN: A nationwide stepped wedge cluster randomised trial in which primary care midwifery practices will be randomised.

PARTICIPANTS: 15,000 women who are still in primary care at 22 weeks gestation and who have a singleton pregnancy.

INTERVENTION AND CONTROL STRATEGIES: In all midwifery practices, growth will be monitored using standardised symphysis fundal height (SFH) measurement according to the KNOV guideline 'Detection of foetal growth restriction'. In the intervention strategy two routine US examinations will be performed (between 28-30 weeks and 34-36 weeks), while in the control strategy US examination will only be performed when clinically indicated. In both groups the IRIS consensus-based protocol will be followed if intrauterine growth retardation is detected.

PRIMARY OUTCOMES: The clinical primary outcome is a dichotomous composite measure 'severe adverse perinatal outcome' up to 7 days after birth, including: perinatal death; Apgar score below 4 at 5 minutes after birth; impaired consciousness; need for assisted ventilation for more than 24 hours; asphyxia; neonatal seizures; septicaemia; meningitis; bronchopulmonary dysplasia; intraventricular haemorrhage; cystic periventricular leukomalacia; or necrotizing enterocolitis. Also direct and indirect costs are primary outcomes.

SAMPLE SIZE: A total of 15,000 women in 60 midwifery practices; 7,500 women per strategy.

MAIN DATA ANALYSIS AND ECONOMIC EVALUATION: Multivariable logistic regression analyses, taking into account the clustered design. The economic evaluation will consist of a cost-effectiveness and a cost-utility analysis and will be performed from both a health care provider and societal perspective. We will base all primary analyses on intention to treat.

DURATION: 48 months.

Study objective

Of all babies that die after 25 or more weeks gestation, 40% are small-for-gestational-age (SGA). In the Netherlands third trimester ultrasonography (US) is increasingly being used to monitor foetal growth even though evidence on its effectiveness or cost-effectiveness is lacking. The proposed study will evaluate the effectiveness and cost-effectiveness of third trimester US on severe adverse perinatal outcome among low risk women in primary care.

Study design

Primary outcome: up to 7 days after birth.

For all 15,000 women we will extract data from the following databases: 1) PRN database; 2) ultrasound centres' databases; 3) hospitals' patient records. These databases will be used to collect data on the primary clinical outcome 'severe adverse perinatal outcome' (e.g. Apgar score) and costs (e.g. number of referrals, number of US scans).

A random sample of 300 women receiving the intervention US strategy and 300 women receiving the control US strategy will be asked to complete questionnaires at 22 and 32 weeks gestation during pregnancy, and at 6 weeks and 6 months after birth (n=600 total). Additionally, a non-random sample consisting of 400 women in whom IUGR is suspected will also be asked to complete questionnaires. The questionnaires will collect detailed information on Healthcare utilization related to the pregancy, absenteeism, presenteeism, general quality of life, pregnancy related anxiety, depression, maternal-fetal attachment and client satisfaction with care.

Intervention

In all midwifery practices, growth will be monitored using standardised symphysis fundal height (SFH) measurement. In the intervention strategy two routine US examinations will be performed (between 28-30 weeks and 34-36 weeks), while in the control strategy US examination will only be performed when clinically indicated. In both groups the IRIS consensus-based protocol will be followed if intrauterine growth restriction is detected. The IRIS study is designed as a Nationwide stepped wedge cluster randomised trial in which primary care midwifery practices will be randomised.

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Eligibility criteria

Inclusion criteria

Inclusion criteria MIDWIFERY PRACTICES:
1) midwives have received the post registration training on the new KNOV guideline ‘detection of IUGR’;
2) those who will perform the biometry US have passed tests on quality fetal US.

Inclusion criteria PREGNANT WOMEN:
1) negative 20 week US screening test result;
2) singleton pregnancy;
3) receiving care in primary care at 22 weeks gestation.

Exclusion criteria

Exclusion criteria PREGNANT WOMEN:
Women without dating US who do not have a reliable estimated date of delivery (EDD).

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2015

Enrollment:	15000
Type:	Anticipated

Ethics review

Positive opinion

Date:	20-03-2014
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	NL4214
NTR-old	NTR4367
Other	ZonMw : 209030001

Study results

Summary results
N/A