IRIS study - The IUGR Risk Selection Study.

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23334

Bron
NTR

Verkorte titel
IRIS - IUGR RIsk Selection

Aandoening

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

Ondersteuning

Primaire sponsor: VU University Medical Center Amsterdam
Overige ondersteuning: ZonMw - Netherlands Organisation for Health Research and Development

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2015
Aantal proefpersonen:	15000
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	20-03-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4214
NTR-old	NTR4367
Ander register	ZonMw : 209030001

Resultaten

Samenvatting resultaten
N/A