Voorspellen van de individuele kans op zwangerschapscomplicaties met behulp van een risico-analyse instrument

No registrations found.

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

Summary

ID

NL-OMON23063

Source
NTR

Brief title
EXPECT study

Health condition

Preeclampsia, gestational diabetes, preterm birth, small-for-gestational-age and large-for-gestational-age.

Preeclampsie, zwangerschapsdiabetes, vroeggeboorte, groeivertraging en macrosomie

Sponsors and support

Primary sponsor: Maastricht University
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

Primary outcome measure is a composite measure of perinatal death, asphyxia, admission to a neonatal intensive care unit, small-for-gestational-age p2.3 and very preterm birth (<32 weeks).

Secondary outcome

- Severe preeclampsia (leading to delivery before the 34th completed week)

- Maternal patient satisfaction

- Maternal health-related quality of life

- Small-for-gestational age (
- Preterm birth (<37 weeks)

- Instrumental delivery (including caesarean sections)

- Process indicators

- Costs

Study description

Background summary

Rationale: First-trimester risk selection may benefit from the use of obstetric prediction rules. A number of first-trimester prediction models have been published, addressing important obstetric outcomes including preterm birth, preeclampsia, gestational diabetes mellitus, small-for-gestational-age and large-for-gestational-age. None of them have however been externally validated (for the Dutch situation). Furthermore, it is not clear whether the use of such prediction rules improves child and maternal outcomes, and how costs are affected. Objectives: 1) To evaluate the predictive performance of promising first-trimester obstetric prediction rules, containing variables that are easily obtainable without any additional costs (history and/or routine antenatal tests), published in the literature. 2) To compare performances of first-trimester obstetric prediction rules with similar health outcomes. 3) To determine the best cut-off values for application of the prediction rules in Dutch obstetric care. 4) To measure the effects of applying first-trimester obstetric prediction rules followed by tailored care paths in Dutch obstetric practice, as compared to care-as-usual. 5) To evaluate cost-effectiveness of applying first-trimester obstetric prediction rules followed by tailored care paths in Dutch obstetric practice, as compared to care-as-usual.

Design: The EXPECT project is a Dutch, multicenter, prospective cohort study that

compromises a validation study and an impact study. In the validation study, we will evaluate the predictive performance of promising first-trimester obstetric prediction rules published in the literature. In the impact study, we will evaluate outcomes and costs after applying 1st-trimester prediction rules followed by tailored care paths, and compare these with outcomes and costs during care-as-usual.

Participants: Eligible for both the validation and the impact study are pregnant women who pay their initial visit to a midwive or gynecologist participating in the Limburg Obstetric Consortium. Exclusion criteria: gestational age >15+6 weeks and age <18 years. A total of 2 x 2750 women will be recruited.

Sample size: phase 1 n=2750 and phase 2 n=750

Main study outcomes: Composite outcome of perinatal death, asphyxia, admission to a neonatal intensive care unit, small-for-gestational-age p2.3, and very preterm birth (<32wks).

Data sources: online questionnaires and patient records.

Analysis: Predictive performance of each prediction rule will be evaluated by assessing the area under the receiver operating characteristic curve (AUC) and model calibration. Final selection of prediction rules and definition of cut-off points will be combined with the definition of tailored care paths for the impact study. Outcomes in the two study arms will be compared by use of either logistic regression or linear regression. Economic analysis: two incremental cost-effectiveness ratios will be calculated expressing 1) the cost per one composite adverse outcome prevented and 2) the cost per Quality Adjusted Life year (mother unit of analysis).

Discussion: first-trimester obstetric prediction rules can lead to improved outcomes for mother and child if they can guide effective actions that are tailored to individual risk profiles.

Time schedule (66 months): preparation time (1-6), recruitment and follow-up phase 1 (7-30), analysis, selection of prediction rules and determination cut-off-points 6 months (31-43),

recruitment and follow-up phase 2 (44-60), data analysis and report (61-66)

Study objective

First-trimester obstetric prediction rules can lead to improved outcomes for mother and child if they can guide effective actions that are tailored to individual risk profiles.

Study design

Phase 1 External validation: 01-12-2012 till 31-12-2015

Phase 2 Impact study: 17-04-2017 till 31-09-2018

Phase 1: online questionnaire before 16 weeks of gestation. Primary outcomes Phase 1 and 2: patient questionnaire (4 weeks postpartum) and patient records. Maternal satisfaction, quality of life and costs: a representative sample of participants (n=750) will be asked to fill out three additional questionnaires (~24 weeks, ~34 weeks and 4 weeks postpartum).

Intervention

Phase 1: No intervention

Phase 2: Application of first-trimester obstetric prediction rules followed by tailored care paths

Contacts

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Eligibility criteria

Inclusion criteria

- Gestational age <16 weeks

- Maternal age 18 years or older

Exclusion criteria

- Gestational age >15+6 weeks

- Maternal age <18 years

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2012
Enrollment:	5500
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	21-08-2013
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	NL3963
NTR-old	NTR4143
Other	METC azM/UM : 13-4-053
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A