Het Foliumzuur-Extra bij kinderwens en zwangerschap onderzoek Noord-Nederland.

No registrations found.

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

Summary

ID

NL-OMON26064

Source
Nationaal Trial Register

Brief title
FoliumzuurExtra

Health condition

Neural Tube Defects (NTDs)
Congenital Anomalies
Preterm Birth
Preeclampsia
Folic Acid supplementation

Neuralebuisdefect
aangeboren aandoening/aangeboren afwijking
vroeggeboorte
pre-eclampsie/zwangerschapsvergiftiging
Foliumzuursuppletie

Sponsors and support

Primary sponsor: VU University Medical Center
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

The primary outcome measures are: FA related congenital anomalies and preterm birth. Information on all congenital anomalies of live births, stillbirths and terminations of pregnancy following prenatal diagnosis will be derived from the database of EUROCAT, where virtually all congenital anomalies are registered. Data about the diagnosis and the medical history are collected in a standardized procedure of high quality. FA related congenital anomalies are neural tube defects, heart anomalies, limb defects, urinary tract malformations, oral cleft and Down syndrome. The congenital anomalies will be classified according to the guidelines for case classification by Rasmussen et al (2003).
Preterm birth is defined as a gestational age < 37 weeks. Gestational age will be assessed from the medical records. Medical terminations will also be included, to avoid bias toward the null hypothesis.

Secondary outcome

1. Birth weight, obtained from medical records;

2. Preeclampsia (defined as a systolic blood pressure > 140 mmHg and/or diastolic blood pressure > 90 mmHg after 20 weeks of gestation among women with previously normal blood pressure, combined with proteinuria (> 300 mg/24 hours)), obtained from medical records;

3. Compliance with intervention.

Study description

Background summary

N/A

Study objective

1. What is the effect of a high (4.0 mg) versus low (0.4 mg) dose of folic acid supplementation from 4 weeks before conception to 12 weeks after conception on the prevalence of folic acid related congenital anomalies?

2. What is the effect of 0.8 mg folic acid supplementation versus 0.2 mg folic acid supplementation from 12 weeks after conception to the end of pregnancy on the prevalence

of preterm birth and preeclampsia?

Study design

After randomisation, women will collect new pills every 16 weeks at the pharmacy, until a period of 12 months has gone by without them getting pregnant or until the end of their pregnancy (live birth, stillbirth, spontaneous abortion, or termination). At each collection date, they fill in a short questionnaire.

Intervention

Women in all intervention groups will receive identical pills, containing two different doses of folic acid (0.4 or 4.0 mg). Women will start taking the pills after randomisation, but at least 4 weeks before conception, and will receive new pills from their pharmacy every 16 weeks.

Fourteen weeks after the first day of the last menstruation (12 weeks after conception), all women will receive a new set of pills, half of them will receive 0.2 mg supplements and half will receive 0.8 mg of FA.

Contacts

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Eligibility criteria

Inclusion criteria

All women living in the Northern region of the Netherlands of 18 to 45 years old who want to become pregnant within 12 months are eligible for participation in the study. Women followed by an assisted reproduction centre are not excluded.

Exclusion criteria

1. No informed consent given;

2. Not understanding Dutch;

3. Already pregnant at time of inclusion or within 4 weeks after start intervention;

4. Planning to move to an area where the study is not implemented;

5. Recently or at present using folic acid antagonists or antifolates or other drugs influencing the folic acid metabolism (anti-epileptica, methotrexaat, pyrimethamine, trimethoprim);

6. Being affected by diabetes, megaloblastic anaemia and/or cancer (previous cancer or abnormal PAP smears);

7. Being allergic to folic acid or any other ingredient of the pills used in this study;

8. Take defined dosages of folic acid for directions other than those listed in the above exclusion criteria.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2012
Enrollment:	5000
Type:	Anticipated

Ethics review

Positive opinion

Date:	22-11-2011
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	NL3013
NTR-old	NTR3161
Other	EudraCT number : 2011-003325-10
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A