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

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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...

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

Samenvatting

ID

NL-OMON26064

Bron
NTR

Verkorte titel
FoliumzuurExtra

Aandoening

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

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

Ondersteuning

Primaire sponsor: VU University Medical Center
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

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?

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2012
Aantal proefpersonen:	5000
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	22-11-2011
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	NL3013
NTR-old	NTR3161
Ander register	EudraCT number : 2011-003325-10
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A