Healthy Pregnancy 4 All - Preconception Care

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The objective of the study is to contibute to the improvement of perinatal outcomes by means of optimisation of preconception care via child wish consulting hours at general practioner and midwife practices.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON41434

Source
ToetsingOnline

Brief title
HP4ALL - PCC

Condition

- Other condition
- Neonatal and perinatal conditions

Synonym
Preconceptional riskfactors for adverse pregnancy outcome, riskfactors in the period before conception for negative pregnancy outcome.

Health condition

Preconceptiezorg is primair gericht op vermindering van risicofactoren voor ongewenste zwangerschapsuitkomsten.

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Subsidie van het Ministerie van VWS

Intervention

Keyword: High risk groups, Implementation research, Perinatal health, Preconception Care

Outcome measures

Primary outcome

Effectivity of preconception care - in terms of risk reduction and lifestyle

changes - in women with a wish to become pregnant. Willingness of women in

areas with a high risk of negative perinatal outcomes to participate in child

wish consultancy hours.

Secondary outcome

N.a.

Study description

Background summary

The unfavourable position of the Netherlands in the European perinatal mortality rates is remarkable considering the good relative prosperity position of the Netherlands. Preconception care is a possibility to eliminate riskfactors for perinatal morbidity and mortality before they can influence the embryo development and early placenta development negative. This leads to a reduction of risks during pregnancy. Besides the individual risk profile of the pregnant woman, unsufficient risk selection is possibly debit to the mean increased mortality and the considerable differences in the Netherlands.

Study objective

The objective of the study is to contibute to the improvement of perinatal outcomes by means of optimisation of preconception care via child wish consulting hours at general practioner and midwife practices.

Study design

Prospective cohort study in 14 high risk cities in the Netherlands.

Intervention

The child wish consulting hour exists of 2 visits. During these visits an individual preconceptional advice will be formulated (visit 1) and evaluated (visit 2). Before eacht visit, participants will fill out a questionnaire and after the visits biomarker research will be done, aimed at lifestyle changes.

Study burden and risks

The discussing of riskfactors before pregnancy is am advancing in the moment at which in standard care risks will be discussed. This gives extra opportunities towards prevention, but might also be experienced to be a burden. In preconceptions consults in general practioners practices however no rise in fear has been measured between the intervention group and the control group. Immediately after the consult a decrease in fear was found.

The participants will be asked to undergo blood samplings twice and to collect a urine sample twice.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Women with a wish to become pregnant, aged 18-41 years, living in a selected city.

Exclusion criteria

• Women who are already pregnant or women with individual circumstances for which they should be excluded, specified by the general practitioner;
• Individual patientfactors for exclusion will be specified by the general practitioner. These can be: on medical grounds (e.g. absolute infertility (hysterectomy), subfertility with active treatment or a terminal disease) or on social grounds (e.g. recent divorce). The goal of the exclusion posibilities is that the general practitioner must be able to safegaurd the physician - patient relationship.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-02-2013

Enrollment:	839
Type:	Actual

Ethics review

Approved WMO Date:	15-11-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-11-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-04-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL40845.078.12