

Obesity in pregnancy.

Published: 14-12-2007

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Obesity-related factors rather than obesity itself predispose to complications in pregnancy.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20635

Source

Nationaal Trial Register

Brief title

N/A

Health condition

1. Obesity;
2. Pregnancy.

Sponsors and support

Primary sponsor: Academic Hospital Maastricht

Source(s) of monetary or material Support: Academic Hospital Maastricht

Intervention

Outcome measures

Primary outcome

A complicated pregnancy defined by the presence of one of the following complications:

1. gestational diabetes;
2. macrosomia;
3. prolonged pregnancy;

4. hypertensive disorder;
5. dysmaturity;
6. preterm birth and/or intrauterine death.

Secondary outcome

Labor complications.

Study description

Background summary

Obese pregnant women have an increased risk to develop both complications in pregnancy and during labor. The obstetrical care system in the Netherlands offers the opportunity for home delivery in healthy low-risk pregnant women. However, save and thus adequate functioning of this system depends on the selection procedure to timely identify and refer high-risk women to the so-called “second-line” care, provided by gynecologists in community hospitals. The objective of this study is to improve early identification of high-risk women among healthy obese pregnant women. Therefor, 90 obese and 90 non-obese nulliparous women will be invited to participate at the time of booking for their prenatal check-ups in a midwifery practice. At twelve weeks of gestation we will perform a couple of measures, consisting of anthropometric parameters, standardized questionnaires on food intake and physical activity, a submaximal fitness test and the measurement of a number of variables in a blood sample.

Study objective

Obesity-related factors rather than obesity itself predispose to complications in pregnancy.

Study design

N/A

Intervention

None. Observational study in which an experimental group of 90 obese pregnant women will be compared to a reference group of 90 non-obese pregnant women.

Contacts

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Eligibility criteria

Inclusion criteria

1. Nulliparous;
2. >18 years;
3. Dutch speaking.

Exclusion criteria

An indication for hospital care present at booking.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-01-2008

Enrollment: 180
Type: Anticipated

Ethics review

Positive opinion
Date: 14-12-2007
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 31473
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1128
NTR-old	NTR1163
CCMO	NL17877.068.07
OMON	NL-OMON31473

Study results

Summary results
N/A