The effect of an exercise program on insulin sensitivity and plasma glucose levels in women at risk for gestational diabetes mellitus.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON33591

Source
ToetsingOnline

Brief title
Fit For 2 Study

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Maternal complications of pregnancy

Synonym
bloodsugar level, Gestational diabetes mellitus, insulin sensitivity

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: ZonMw (en extra financiering voor interventie door bedrijven/industrie wordt nog aangevraagd)

Intervention

Keyword: exercise, gestational diabetes, physical activity, prevention

Outcome measures

Primary outcome

Measurements will be conducted before randomisation (around 15 weeks of pregnancy), at 24 and 32 weeks of pregnancy and 12 weeks postpartum.

Primary maternal outcome measures are fasting plasma glucose and relative increase in insulin resistance. Primary neonatal outcome is birth weight.

Secondary outcome

Secondary outcome measures are: maternal serum triglycerides, maternal bodyweight gain during pregnancy, maternal physical activity level, fetal growth.

Study description

Background summary

Pregnancy is a period in the live of women that may result in decreased daily physical activity and/or exercise. This change often occurs despite the fact that there is no medical reason for women to reduce their daily physical activity levels and/or exercise. However, maintaining adequate levels of daily physical activity during pregnancy may be important for mother and child. Studies of daily physical activity or exercise and the occurrence of maternal pregnancy related disorders suggest that moderate daily physical activity and exercise during pregnancy may be associated with reductions in the risk of gestational diabetes mellitus (GDM). However, at the moment, physical activity is not routinely advised or prescribed for women at risk for gestational

diabetes in the Netherlands.

Study objective

The overall aim of the study: To assess whether an exercise program can improve insulin sensitivity and fasting plasma glucose levels of women at high risk for gestational diabetes, assuming that this will normalise their risk of gestational diabetes. Secondary objectives: Measure the effect of an exercise program on birth weight and the compliance with the exercise program and what factors contribute to the success or failure of the program.

Study design

This study is a randomised controlled trial. 160 women at risk for gestational diabetes will be randomly allocated to two groups; an intervention (n = 80) and a control group (n = 80).

Intervention

The intervention group will receive a twice a week an exercise program in addition to usual care, and the control group will receive usual care.

Study burden and risks

The intervention will be an exercise program twice a week during the remaining duration of the pregnancy. Trainers have expertise with providing training for pregnant women. Exercises will be adjusted to the fitness and endurance level of the women at the start of the intervention and later on to their stage of pregnancy. When they follow the guide of the ACOG the exercise program will be safe and healthy.
The training program will take some time from the women, but it will lower the risk of gestational diabetes. The measurements do not pose a risk, but it will also take time of the women. However pregnant women are often very motivated participants, especially when it may be important for their pregnancy outcome.

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

Inclusion criteria are:
-between 14 and 20 weeks of pregnancy,
-at risk for gestational diabetes mellitus (GDM),
-over 18 years of age,
-sufficiently fluent in Dutch,
-able to be moderately physically active;Women will be considered to be at risk for GDM when they have:
- BMI * 30
or
- BMI * 25 AND a, b or c
a) history of macrosomia;
b) history of abnormal glucose tolerance;
c) first grade relative with diabetes mellitus type 2.

Exclusion criteria

Exclusion criteria are:
- diagnosed with (gestational) diabetes mellitus before randomisation
- hypertension (systolic pressure > 160mmHg and/or diastolic pressure >100mmHg)
- alcohol abuse (i.e. 2 glasses alcohol or more per day),
- use of drugs (except for incidental analgesic agents)

- serious pulmonary impairment; COPD, exercise-induced asthma
- serious cardiac impairment; angina pectoris, cardiac decompensation, history with cardiovascular disease,
- serious hepatic impairment; 3 times the upper limit of normal,
- serious renal impairment; serum creatinine > 150 *mol/l,
- malignant disease
- serious mental or physical impairment i.e. preventing to understand or implement the study protocol / aim.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-09-2007
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO

Date:	18-07-2007
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL17962.029.07