Vitamin D And Lifestyle Intervention for Gestational Diabetes Mellitus (GDM) Prevention - A European multicentre, randomised trial: Vitamin D limb.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Maternal complications of pregnancy
Study type	Interventional

Summary

ID

NL-OMON39823

Source
ToetsingOnline

Brief title
DALI-Vitamin D

Condition

- Maternal complications of pregnancy

Synonym
gestational diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: Gestational diabetes, Lifestyle, Prevention, Vitamin D

Outcome measures

Primary outcome

Maternal

* gestational weigth gain

* fasting plasma glucose

* insulin sensitivity

Foetal

* birth weight and length

Secondary outcome

Maternal:

* blood pressure

* lifestyle

Foetal

* Placenta weight

* neonatal body composition

* Neonatal head and abdominal circumference

* Neonatal clinical outcomes (APGAR values, neonatal hypoglycaemia,

hyperbilirrubinaemia, respiratory distress, hypomagnesemia, neonatal mortality,

stillbirth, early neonatal death, perinatal death)

Study description

Background summary

Gestational Diabetes (GDM) is defined as 'carbohydrate intolerance resulting in hyperglycaemia of variable severity with onset or first recognition during pregnancy'. The prevalence of GDM in Europe is reported to vary considerably, in some populations GDM occurs already in up to 20 % of all pregnancies. There are few published studies about preventing GDM.

Study objective

The overall aim of the DALI study is to identify the best available measures to prevent GDM in an ongoing pregnancy, to provide a cost-benefit calculation of GDM prevention for health care systems, and to establish a pan-European cohort of mother-offspring pairs for future analyses with a central biobank and data base. For this purpose, a randomised controlled trial will be conducted in 10 European countries.

Study design

This is a multicentre, randomised trial across 10 European countries.

In this main trial, 880 participants will be randomised.

In essence the study consists of two trials conducted in parallel:

Trial 1:
1) counseling healthy diet
2) counseling physical activity
3) counseling physical activity & healthy diet
4) control group

Trial 2:
5) counseling physical activity & healthy diet & placebo
6) vitamin D (1600 IU/day)
7) counseling physical activity & healthy diet & vitamin D (1600 IU/day)
8) placebo.

1) physical activity, diet and physical activity and diet) or a control group.
The trial will be conducted in 10 European countries and in each country 44

women, without GDM, will be recruited (total n = 440) before 20 weeks of pregnancy.

Intervention

In the programme, one-to-one contact will be offered, along with telephone booster calls. The same amount of time will be offered to each participant during the trial. The intervention will be provided in five sessions of approximately 30-45 minutes, and in four telephone calls of approximately 20 minutes. The on-to-one sessions will take place at the home of the participants or in hospital/midwife practice/general practice, depending on cultural acceptability of home visits. To optimize rapport, it is expected that a lifestyle coach is made responsible for supporting a defined number of participants throughout the pregnancy period. The coach will have a PDA which will provide the framework for the visit and will help steer the coach to deliver the nutrition and/or physical activity package. Details will be entered into the PDA programme and at the end of the session, the synchronization button will be pressed to send the recorded data to the Trial coordination team.

* Physical activity
According to the ACOG guidelines, pregnant women are recommended to be moderately physically active for at least 30 minutes per day on at least 5 days of the week [13]. Given our population of obese women, low fitness and physical activity levels are to be expected. Activities such as swimming, walking and cycling are activities that the participants should be able to undertake during the course of their pregnancy. As pregnancy progresses through the third trimester, physical activity may decrease and this needs to be managed sympathetically, providing e.g. sitting and/or upper limb exercises as alternatives. They are advised to (1) incorporate active movement as much as possible into their daily life
(e.g. by parking further away from destination), (2) reduce sedentary time, (3) incorporate upper and or lower limb resistance exercise as physical activity, (4) to increase the number of steps taken per day and (5) to be more active during the weekends. An action plan for increasing physical activity levels will be made during the first session, and evaluated in subsequent sessions. Participants will receive pedometers for feedback on their behaviour and progress.

* Diet
The following dietary objectives will be set for each participant to achieve or to maintain: (1) to reduce intake of sugary drinks (replace with water), (2) to eat more non-starchy vegetables, (3) to choose high-fibre, over low fibre products (*5 g fibre/100 g), (4) to watch portion size, (5) to increase intake of proteins (e.g. meat, fish, beans), (6) to reduce fat intake (e.g. snack, candy, fast food, fried foods), and (7) to reduce intake of carbohydrates (e.g. potatoes, pasta, rice, snacks, candy) . An action plan for improving dietary behaviour will be made during the first session, and evaluated in subsequent

sessions.

Coaches
Members of the research team will carry out the face-to-face counselling and the telephone booster sessions. They will receive a special training programme containing motivational interviewing techniques to overcome the ambivalence or barriers that keeps people from making desired lifestyle changes in their lives.

Study burden and risks

Risks and burden to the participant:
* Clinical assessments
There are 4 study assessment visits over 6-7 months. The assessments consist of: urine samples, blood samples (including OGTT), ultrasound, body weight measurement, and filling out questionnaires. Height will be measured at baseline.
Most assessments can be performed shortly after a routine appointment to the obstetrician / midwife, removing the need to have study-specific hospital visits. The measurements will add approximately 30 minutes to a routine appointment. The OGTT will take 2.5 hours. Venepuncture has a risk of bruising and discomfort, but there is no risk of serious harm.

* Interventions
Women will be asked to take a daily dose of 1600 IU vitamin D supplementation, which will not be a burden for the participants.

Potential risks of Vitamin D supplementation:
Vitamin D supplementation can potentially entail the risk of intoxication which would be a serious complication that is virtually impossible at the doses tested. Other potential risks are maternal hypercalciuria/nephrolithiasis and allergy/asthma in the infant; they also seem unlikely at the doses used. In addition, hypercalcaemia and hypercalciuria have been included as exclusion/stop criteria to further minimize the risk.
It is important to highlight that even for women receiving 1600 IU/day, after adding diet and multivitamin supplementation, the UL of the recommended dietary intake of 4000 IU/day will not be surpassed. We also want to highlight that the doses used will be lower than those currently used in other trials that have not reported adverse consequences so far:

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(http://clinicaltrials.gov/ct2/show/NCT00856947?term=vitamin+D+pregnancy&rank=2,
http://clinicaltrials.gov/ct2/show/NCT00610688?term=vitamin+D+pregnancy&rank=4
* http://clinicaltrials.gov/show/NCT00292591
* http://clinicaltrials.gov/ct2/show/NCT00920621

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* pre-pregnancy BMI (self-reported weight, measured height) is * 29 kg/m2);* aged 18 years or more;* singleton pregnancy;* gestational age at recruitment < 20 weeks;* sufficiently fluent in major language of the country of recruitment;* being able to be moderately physically active;* giving written informed consent

Exclusion criteria

* preexisting diabetes;* Diagnosed with (gestational) diabetes mellitus before randomisation defined as fasting glucose * 5.1 mmol/l and/or 1 hour glucose * 10 mmol/l and/or 2 hour glucose *8.5 mmol/l at baseline measurement.;* not able to walk at least 100 meters safely;* requirement for complex diets;* advanced chronic conditions (e.g. valvular heart disease);*

significant psychiatric disease;* unable to speak major language of the country of recruitment fluently

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-06-2013
Enrollment:	44
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Cholecalciferol / vitamin D3
Generic name:	Vitamin D
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	21-02-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO Date:	27-05-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-07-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-04-2014
Application type:	Amendment
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
EudraCT	EUCTR2013-000789-13-NL
ISRCTN	ISRCTN70595832
CCMO	NL42534.029.12