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Vitamin D and lifestyle Intervention for gestational diabetes mellitus (GDM) prevention

Submission date
21/11/2011

Recruitment status
No longer recruiting

Registration date
02/12/2011

Overall study status
Completed

Last Edited
05/01/2021

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
When Diabetes Mellitus is first found during pregnancy it is called Gestational Diabetes Mellitus (GDM). Women with GDM have high levels of glucose (sugar) in their blood. This can have severe consequences for mothers and their children. Prevention of GDM is therefore important. The main aim of this study is to evaluate the effects of three interventions to prevent GDM.

Who can participate?
Obese pregnant women before 12 weeks of pregnancy

What does the study involve?
This study looks at the effects of advice on physical activity, advice on diet, vitamin D supplementation, and combinations of these. Participants are randomly allocated to one of the several treatments that are compared. Those allocated to the lifestyle interventions (physical activity, diet or a combination of these two) have personal contact with a lifestyle coach as soon as possible after inclusion in the study. The same coach delivers the nutrition and/or physical activity interventions. Women have five face-to-face sessions with their coach, and three telephone sessions. Women in the vitamin D groups take vitamin D supplements until delivery. The levels of glucose and insulin in the women's blood are measured at the start of the study and at 24-28 and 35-38 weeks of pregnancy. Weight gain during pregnancy is also measured.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
1. Institut de Recerca de l'Hospital de la Santa Creu, Barcelona, Spain
2. Cambridge University Hospitals (NHS) Cambridge, UK (trial coordinator)
3. Medical University, Vienna, Austria
4. Katholieke Universiteit, Leuven, Belgium
5. Copenhagen University Hospital, Copenhagen, Denmark
6. Akademia Medyczna im Karola Marcinkowskiego, Poznan, Poland
7.Università degli studi di Padova, Padova, Italy
8. National University of Ireland, Galway, Ireland

9. VU University Medical Center, Amsterdam, the Netherlands
10. University Hospital, Odense, Denmark

When is the study starting and how long is it expected to run for?
September 2012 to September 2014

Who is funding the study?
European Union (EU) 7th Framework Programme for Research

Who is the main contact?
1. Dr David Simmons (trial coordinator)
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2. Dr Mireille van Poppel (sponsor)
mnm.vanpoppel@vumc.nl
3. Univ.-Prof. Dr. Gernot Desoye (DALI project coordinator)
gernot.desoye@medunigraz.at

Study website
http://www.dali-project.eu

Contact information

Type(s)
Scientific

Contact name
Dr David Simmons

ORCID ID
http://orcid.org/0000-0003-0560-0761

Contact details
University of Western Sydney
Locked Bag 1797
Penrith
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NSW 2751

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 1

Study information

Scientific Title
DALI: Vitamin D And Lifestyle Intervention for gestational diabetes mellitus (GDM) prevention: a randomised controlled trial

Acronym
DALI

Study objectives
The DALI project aims to identify the best available measures to prevent GDM in an ongoing pregnancy.
Specific objectives are:
1. To compare the impact of increased physical activity, enhanced nutrition and Vitamin D supplementation either alone or in combination on maternal glucose tolerance, maternal weight gain and insulin sensitivity
2. To do an evaluation of barriers and promoters of uptake in life style changes
3. To provide a cost-benefit calculation of GDM prevention for health care systems

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial with a factorial design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Gestational diabetes

Interventions
Interventions section as of 09/06/2016:
The design is that of two trials with a factorial design:

Trial 1:
1. Physical activity (PA)
2. Diet
3. PA & diet
4. Control

Trial 2:
1. Vitamin D
2. PA & diet and placebo
3. Vitamin D & PA & diet
4. Placebo

In each of the lifestyle interventions (physical activity, diet or a combination of these two), women will have personal contact with the lifestyle coach as soon as possible after randomisation. The same coach will deliver the nutrition and/or physical activity interventions. Each coach will have a desk-file outlining the intervention and options in detail.

The first phase of behaviour change for both physical activity and diet is centred around intention formation. Education on risks and benefits, enhancing positive outcome expectancies and self-efficacy beliefs will be the primary task, translating into goal setting, action planning and reinforcement. Following realistic goal setting, the women need to be encouraged and supported in their efforts to eat healthy and/or to be sufficiently physically active. During this action phase behavioural strategies will be provided (e.g. cueing, mental imaging, self-monitoring) along with mobilising social support and identifying and overcoming obstacles where possible. The support programme builds on patient empowerment and cognitive behavioural principles, utilising techniques from Motivational Interviewing.

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.

In the Vitamin D intervention, women will use 1600 IU vitamin D supplements per day from the start of the intervention until delivery.

Original Interventions section:
The design is that of two trials with a factorial design:
1. Physical activity (PA)
2. Diet
3. PA & diet
4. Control
5. Vitamin D
6. PA & diet and placebo
7. Vitamin D & PA & diet
8. Placebo

In each of the lifestyle interventions (physical activity, diet or a combination of these two), women will have personal contact with the lifestyle coach as soon as possible after randomisation. The same coach will deliver the nutrition and/or physical activity interventions. Each coach will have a desk-file outlining the intervention and options in detail.

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The doses of Vitamin D that will be tested in the dosing study are 500, 1000 and 1500 IU/day. One of these doses will be used in the trial.

Intervention Type
Mixed

Primary outcome measure
1. Weight gain during pregnancy: women will be weighed at all three measurements, with a calibrated scale (Seca)
2. Fasting plasma glucose: The fasting plasma glucose test is performed after a person has fasted for at least 8 hours. A sample of blood is taken from a vein (antecubital region) in the arm
3. Insulin sensitivity will be measured using Homeostatic Model Assessment (HOMA), Quantitative insulin sensitivity check index (QUICKIE) and oral glucose insulin sensitivity (OGIS). OGIS also enables evaluation of insulin secretion. First phase insulin response will be calculated from the fasting and 30 min samples

Secondary outcome measures
Maternal parameters:
1. HbA1c, fasting C peptide, leptin, triglycerides, free fatty acids, high density lipoprotein cholesterol (HDL-C) and low density lipoprotein cholesterol (LDL-C), adiponectin
2. 3 beta-hydroxy-butyrate will be used as measures of alternative fuel supply; the latter also potentially a measure of excess weight loss and for safety studies
3. Blood pressure
4. C-reactive protein (CRP) will be measured as an indication for maternal inflammation
5. Change in physical activity will be assessed with a validated physical activity questionnaire and by accelerometer
6. Change in dietary habits will be assessed with a short food frequency questionnaire
7. All costs related to pregnancy and delivery: direct health care and non-health care costs and indirect non-health care costs will be assessed prospectively by questionnaires

Foetal parameters:
1. For the assessment of how GDM affects the foetus, antenatal growth protocols for the following measurements will be developed: neonatal growth, adiposity, adipo-insular axis, glucose-insulin axis, electrolyte concentrations, clinical outcomes and hypoxia exposure at birth.

Clinical measurements will be performed in all trial centers, laboratory measurements in the central laboratory on the samples collected in all trial centers.
This will include:
1.1. Prenatally standardised ultrasound assessment of classic foetal growth parameters [biparietal diameter (BPD), head circumference (HC), abdominal circumference (AC), femur length (FL)] and determinants of foetal body composition variables (lean body mass and fat body mass).
1.2. At birth the following parameters will be recorded: Placental weight, birth weight and length, head and abdominal circumference, skin fold thickness (subcutaneous adipose tissue). In addition cord blood (arterial and venous) will be collected by all centers and sent to the central laboratory to measure C-peptide, glucose, leptin, triglycerides, 3- beta-hydroxy-butyric acid, pH and erythropoietin (EPO). A serum store will be kept for future analyses (where sufficient is available).
1.3. After birth clinical outcomes such as jaundice, hypocalcaemia, hypomagnesaemia, neonatal intensive care unit (NICU) admission, respiratory distress will be recorded

Overall study start date
01/09/2012

Completion date
01/09/2014

Eligibility

Key inclusion criteria
1. Pre-pregnancy body mass index (BMI) (self-reported weight, measured height) is >= 29 kg/m2)
2. Aged 18 years or more
3. Gestational age at recruitment < 12 weeks
4. Sufficiently fluent in major language of the country of recruitment
5. Being able to be moderately physically active
6. Giving written informed consent
7. Agree to give birth in one of the participating hospitals

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
880

Total final enrolment
693

Key exclusion criteria
1. Pre-existing diabetes
2. 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
3. Not able to walk at least 100 meters safely
4. Requirement for complex diets
5. Advanced chronic conditions (eg valvular heart disease)
6. Sgnificant psychiatric disease
7. Unable to speak major language of the country of recruitment fluently
8. Known abnormal calcium metabolism (hypo/hyperparathyroidism, nephrolithiasis, hypercalciuria) or hypercalciuria detected at screening (0.6 mmol/mmol creatinine in spot morning urine)
9. Twin pregnancy

Date of first enrolment
01/09/2012

Date of final enrolment
01/09/2014

Locations

Countries of recruitment
Austria

Belgium

Denmark

England

Ireland

Italy

Netherlands

Poland

Spain

United Kingdom

Study participating centre
Addenbrooke's Treatment Centre
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
VU University Medical Center (Netherlands)

Sponsor details
Van der Boechorststraat 7
Amsterdam
Netherlands
1081 BT

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Government

Funder Name
Seventh Framework Programme

Alternative Name(s)
EC Seventh Framework Programme, European Commission Seventh Framework Programme, EU Seventh Framework Programme, European Union Seventh Framework Programme, FP7

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date

31/10/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	05/07/2013		Yes	No
Results article	results	01/09/2015		Yes	No
Other publications	process evaluation	07/09/2017		Yes	No
Results article	cost-effectiveness results	14/03/2018		Yes	No
Results article	results	01/08/2019	15/04/2020	Yes	No
Other publications	review	16/12/2019	28/05/2020	Yes	No
Results article	results	01/04/2020	05/01/2021	Yes	No