A randomized clinical trial to study the effect of vitamin D supplementation on insulin sensitivity in Gestational Diabetes Mellitus

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The main objective is to study the effect of vitamin D supplementation on insulin sensitivity in patients with gestational diabetes mellitus.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Diabetic complications
Study type	Interventional

Summary

ID

NL-OMON39103

Source
ToetsingOnline

Brief title
Vitamin D supplementation in Gestational Diabetes

Condition

- Diabetic complications
- Pregnancy, labour, delivery and postpartum conditions

Synonym
Gestational diabetes mellitus; diabetes in pregnancy

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Alkmaar

Source(s) of monetary or material Support: Medisch Centrum Alkmaar;interne geneeskunde

Intervention

Keyword: gestational diabetes mellitus, glucose metabolism, insulin sensitivity, vitamin D

Outcome measures

Primary outcome

Insulin sensitivity

Secondary outcome

Secondary outcomes are to examine the predictive value of patient-related factors in terms of changes in serum 25-hydroxyvitamin D (25OHD) and glycemic control. Also the fasting glucose and glucose variation, HbA1c, insulin dose, blood pressure, lipid profile, thyroid function and urine analysis during supplementation of vitamin D in gestational diabetes is assessed. AGE accumulation in the skin.

Study description

Background summary

Gestational diabetes mellitus (GDM) is a substantional and world wide growing health concern affecting approximately 10% of all pregnancies. GDM has serious outcomes for both mother and child. Many research is conducted to identify which factors increase the risk for GDM, finally to estimate and eventually reduce the risk of GDM. Decreased serum vitamin D has been proposed as one of these factors being associated with GDM. Recent observational studies demonstrated conflicted results between vitamin D deficiency and the diagnosis of GDM. This trial aims to identify the effect of vitamin D supplementation on insulin sensitivity in women with GDM. In the future this may lead to structural vitamin D supplementation during pregnancy

Study objective

The main objective is to study the effect of vitamin D supplementation on insulin sensitivity in patients with gestational diabetes mellitus.

Study design

The trial is a double blind, randomized placebo-controlled trial.

Intervention

Follow-up: onset of GDM till the end of pregnancy

Group 1: Cholecalciferol 15.000IU once a week
Group 2: Placebol 15.000IU once a week

Study burden and risks

The vitamin D dosage is in a safety range and any adverse events are not expected. Recently the institute of medicine recommended a upper limit dose of 4000IE a day in adults not making a difference in pregnancy. A dose of 10.000IE once a day appears to be safe in pregnancy. A total number of 5 visits are scheduled which includes physical examination and a blood sample. The visits will be combined with the regular care for GDM, two extra visits are necessary for the OGTT. Three extra blood samples are required in contrast to the regular treatment. The benefits of participation is that vitamin D may improve the insulin sensitivity which may prevent or reduces antidiabetic therapy. Vitamin D may lead to improvement of maternal en neonatal outcomes as discussed in the literature

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

Written informed consent
Gestational diabetes, defined by the WHO criteria
women 18-42 years old

Exclusion criteria

Pre-existent type of diabetes
serum vitamin D <15 nmol/l or >100nmol/l
impaired renal function with an estimated clearance < 50 mmol/l
hypercalciemia
urolithiasis

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2012
Enrollment:	64
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Cholecalciferol
Generic name:	Cholecalciferol
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	17-04-2012
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	05-06-2012
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	20-07-2012
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)
Approved WMO Date:	15-07-2013
Application type:	Amendment
Review commission:	METC Noord-Holland (Alkmaar)

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	EUCTR2011-005209-60-NL
CCMO	NL38573.094.12