Effect of InsuVital on glucose control in women with gestational diabetes

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Assess whether InsuVital intake improves the postprandial glucose, insulin and C-peptide response

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

Summary

ID

NL-OMON33906

Source
ToetsingOnline

Brief title
InsuVital in gestational diabetes

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Pregnancy, labour, delivery and postpartum conditions

Synonym
Gestational Diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,DSM Food Specialties,het onderzoek wordt mede gefinancierd door DSM

Intervention

Keyword: Gestational diabetes, Glucose control, Insulin, InsuVital

Outcome measures

Primary outcome

4 -h postprandial AUC for blood insulin, glucose and C-peptide after InsuVital

or control drink followed by breakfast at Day 1

Secondary outcome

4 -h postprandial AUC for blood insulin, glucose and C-peptide after InsuVital

or control drink followed by breakfast at Day 8

Changes from baseline in the mean daily postprandial capillary glucose

concentration (3xdaily) during the 7-day Insuvital/control intake period

Changes from baseline in the mean daily capillary glucose AUC (5x daily) during

the 7 day Insuvital/control drink intake period

Daily AUC and time above glucose upper limit (>7 mmol/l) for continuous glucose

measurements at day 2,3,4

Study description

Background summary

InsuVital a casein hydrolysate. stimulates insulin secretion and decreases postprandial glucose levels in patients with type 2 diabetes. InsuVital may fit well in a set of dietary recommendations to manage blood glucose levels, which are typically given in gestational diabetes. As yet no data are available about the effect of insuVital in women with gestational diabetes.

Study objective

Assess whether InsuVital intake improves the postprandial glucose, insulin and

C-peptide response

Study design

Double-blind randomized parallel design

Intervention

25 women will receive 2 dd (before breakfast and dinner) an InsuVital drink and 25 women will receive 2dd (before breakfast and dinner) a control drink

Study burden and risks

The study takes 8 days. The patient will consume 250 ml InsuVital or 250 ml control drink twice daily. Subjects will daily fill in a Food Diary. Daily they will determine a blood glucose curve (five measurements). At day 1 and 8 they will visit the hospital for a four hour measurement period. They will report fasted, receive a catheter into an antecubital vein for blood sampling. In total, 14 x 6.5 ml =91 ml of blood will be sampled over a 4-h period both at day 1 and day 8. After a fasting baseline sample is drawn, subjects will start at t=0 consuming the InsuVital or control drink followed by a standardized breakfast.
The subjects will be asked to wear a continuous glucose monitor for 4 days. The latter is no condition to participate in the study

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

Women with gestational diabetes
Gestational age >= 20wks and <36wks

Exclusion criteria

Diabetes type 1 or type 2
3 times plasma glucose > 9 mmol/l or once plasma glucose > 11 mmol/l
GFR < 60 mL/min/1.73 m2
ALAT > 70 IU/L

Study design

Design

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

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	01-11-2009
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	04-03-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	01-10-2009
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL24605.078.08