Effect of protein hydrolysate on blood glucose control in women with gestational diabetes.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23081

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Women with gestational diabetes mellitus.

Sponsors and support

Primary sponsor: Erasmus Medical Center Rotterdam
Source(s) of monetary or material Support: Erasmus Medical Center Rotterdam and DSM Food Specialties

Intervention

Outcome measures

Primary outcome

4 -h postprandial Area Under the Curve (AUC) for blood insulin, glucose and C-peptide after protein hydrolysate or control drink followed by breakfast at Day 1.

Secondary outcome

1. 4 -h postprandial AUC for blood insulin, glucose and C-peptide after protein hydrolysate or control drink followed by breakfast at Day 8;

2. Changes from baseline in the mean daily postprandial capillary glucose concentration (3xdaily) during the 7-day protein hydrolysate/control intake period;

3. Changes from baseline in the mean daily capillary glucose AUC (5x daily) during the 7 day protein hydrolysate/control drink intake period;

4. Daily AUC and time above glucose upper limit (>7 mmol/l) for continuous glucose measurements at day 2,3,4.

Study description

Background summary

This study is designed to assess whether protein hydrolysate intake improves the postprandial glucose, insulin and C-peptide response in women with gestational diabetes.

Study objective

The protein hydrolysate reduces the postprandial glucose response and increases the insulin and C-peptide response in women with gestational diabetes mellitus.

Study design

1. Baseline;

2. 7½ day intervention.

Intervention

Women will receive either a protein hydrolysate-containing drink or a control drink containing 8.5 g protein hydrolysate dissolved in water that will be consumed twice daily for in total 15 times (i.e., 7½ days), one before breakfast and one before dinner.

Contacts

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Eligibility criteria

Inclusion criteria

1. Gestational age >20 wks and <36 wks;

2. Positive plasma glucose screen or positive 75 g OGTT;

3. Singleton pregnancy;

4. Subject is willing to undergo all protocol related assessments;

5. Subject has read the information provided on the study and given written consent.

Exclusion criteria

1. 3 plasma glucose levels >9 mmol/L or 1 plasma glucose level >11 mmol/L after which subjects will start insulin treatment;

2. Diagnosed type-1 or type 2 diabetes;

3. Renal insufficiency (GFR <60 mL/min/1.73 m2 according to MDRD formula= GFR (mL/min/1.73 m2=1.75 x (0.0113 x s-creat)-1,154 x (age)-0,203x (0.742 for women) multiplied by 1.21 if the patient is black/Afro-Caribbean);

4. Serum ALAT >70 IU/L;

5. Anaemia (Hemoglobin level <7.0 mmol/l);

6. Any clinical condition or laboratory test result that in the opinion of the investigators may jeopardise the health status of the participants;

7. Subjects who are enrolled in an another intervention study or have received an intervention within the last 14 days prior to screening.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2009
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-06-2009
Application type:	First submission

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
NTR-new	NL1738
NTR-old	NTR1848
Other	METC Erasmus : 062374
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A