

Time restricted eating to treat gestational diabetes mellitus

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To determine the effect of time restricted eating in gestational diabetes on glucose metabolism.

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

Summary

ID

NL-OMON55092

Source

ToetsingOnline

Brief title

TRE-GDM

Condition

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

Synonym

gestational diabetes mellitus

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: stichting,fondsen

Intervention

Keyword: diabetes mellitus, gestational diabetes, time restricted eating, TRE

Outcome measures

Primary outcome

Will be assessed at the week following; the start of study, week 4,8 and 12.

- average 2-hour postprandial glucose levels
- average fasting glucose levels

Secondary outcome

- feasibility of study (compliance)
- blood glucose time in range
- average blood glucose values
- Hepatic steatosis and fibrosis
- need for glucose lowering drugs
- neonatal birth weight
- fasting glucose 6 weeks post-partum
- maternal bodyweight gain
- maternal sleep quality
- pregnancy complications
- neonatal complications
- participant satisfaction with the diet

Study description

Background summary

Gestational diabetes mellitus (GDM) has an incidence of 2-5% in the Netherlands, and confers an increased risk of maternal and neonatal complications, including miscarriage, foetal anomalies, pre-eclampsia and macrosomia. Blood glucose reduction reduces this risk of maternal and neonatal complications in GDM.

All mammals have a circadian timing system, consisting of a central brain clock in the hypothalamic suprachiasmatic nucleus (SCN), and peripheral clocks in tissues including liver, muscle, and adipose tissue. The central SCN clock regulates food intake and energy expenditure, and peripheral clocks regulate daily rhythms in local tissue glucose metabolism, with the liver clock regulating gluconeogenesis, the muscle clock regulating insulin sensitivity, and the pancreas clock regulating insulin secretion. Peripheral clocks are not only synchronized by direct signals from the central clock, but also strongly respond to signals resulting from food intake. Time restricted eating (TRE) is the reduction of the eating period to a consistent daily 4-12 hr period. The rationale is that with appropriately timed TRE, the periods of food intake and fasting are synchronized with the rhythm of the circadian timing system, and thereby the functioning of the circadian tissue clocks is improved. Several studies indicate that TRE is a promising new approach in the prevention and treatment of diabetes mellitus. TRE protects against the development of obesity, type 2 diabetes, and non-alcoholic fatty liver disease (NAFLD) in mice fed a high fat diet, and in mice fed a high-fat-high-sucrose diet. In two recent translational human pilot studies, 10-11hr TRE caused persistent weight loss in 8 obese subjects and 6hr TRE improved insulin sensitivity in men with prediabetes. To date, TRE has not been investigated in GDM. We hypothesize that TRE improves insulin sensitivity, glucose values, and consequently neonatal and maternal outcomes in GDM, via strengthening of clock gene expression rhythms.

Study objective

To determine the effect of time restricted eating in gestational diabetes on glucose metabolism.

Study design

prospective single blinded randomized controlled trial

Intervention

The intervention group will adhere to a TRE-regimen in addition to receiving the standard care as is given according to protocol in gestational diabetes mellitus. The control group will solely be given the standard care according to protocol.

Study burden and risks

The study will generate knowledge on the effects of time restricted eating on sugar metabolism in women with GDM. This information is very valuable as GDM with an incidence of 2-5% in the Netherlands confers an increased risk of maternal and neonatal complications. Blood glucose reduction reduces this risk of maternal and neonatal complications in GDM and TRE could prove to be a novel way of achieving this. No benefits for the patients can be guaranteed but adhering to a TRE-regimen in women with GDM could lead to a better glucose control if similar results are found to an earlier study in men with prediabetes.

Study burden and risks are in proportion to the benefits for both society and participants themselves. Participants will be in the study from approximately 28 week pregnancy duration until 6 weeks after delivery (i.e. approximately 12 weeks).

Total study duration is 12 weeks but actual time spent on the study is limited to five short visits.

The burden of participation is minimal. In addition to regular care, participants will

- fill in the Munich Chronotype Questionnaire (MCTQ) and the chrono-nutrition questionnaire (10 min) at inclusion.
- At baseline and at week 4, 8 and 12 after inclusion, participants will:
 - o Keep track of their daily food intake by means of a food diary.
 - o Wear a wrist-worn actigraph, with the look and feel of a regular watch
 - o Fill in the Pittsburgh Sleep Quality Index (a questionnaire which takes approximately 5 minutes to complete)
 - o Collect buccal cytological brushes with 4-hourly intervals during the awake hours. For this they use a non-invasive buccal swab, which has no risks for the participants.
- At the start of the study, week 4 and the visit before the expected delivery date.
 - o Wear a Dexcom G6 glucose monitor. (This is optional; additional permission is asked in the informed consent form).
- At the start of the study, the visit before the expected delivery date and 6 weeks post-partum;
 - o undergo hepatic steatosis measurement with the FibroScan (2-5 min). The FibroScan is a non-invasive ultrasound measurement without any risks for participants (additional permission for this procedure is asked in the informed consent form).
 - o After study completion, undergo an in depth interview about the time-restricted eating regimen (30 minutes)

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

- singleton pregnancy
- diagnosis of GDM (fasting plasma glucose >6.1 mmol/l or 2 hr 75g OGTT value >7.8 mmol/l)
- adequate control of Dutch or English language
- Eating during a period of >11 hours during a typical weekday. (Preliminary data from an ongoing questionnaire study at our centre suggests an estimated 29% of OGTT positive patients already practice TRE by eating ≤ 11 hours during a typical weekday).
- Amenorrhea duration at time of inclusion ≤ 34 weeks

Exclusion criteria

- pre-existing diabetes mellitus
- glucocorticoid induced diabetes mellitus
- non-singleton pregnancy
- circadian rhythm sleep disorders as defined in the DSM-5
- shift work during pregnancy

- repeatedly crossing >2 time zones during pregnancy

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	20-05-2021
Enrollment:	38
Type:	Actual

Ethics review

Approved WMO	
Date:	21-07-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	09-03-2022
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
CCMO	NL71141.018.19