Time restricted eating to treat gestational diabetes mellitus

No registrations found.

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

Summary

ID

NL-OMON23529

Source
Nationaal Trial Register

Brief title
TRE-GDM

Health condition

Gestational diabetes mellitus

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Asklepios foundation, Fonds Parkherstellingsoorden, Amsterdam Gastroenterology Endocrinology Metabolism research institute

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

• blood glucose time in range
• average blood glucose
• 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) poses major health risks to a pregnant woman and the fetus. It has been proven that the reduction of glucose levels in GDM reduces pregnancy complication risks. Dietary advice is the first step in the treatment of gestational diabetes mellitus, but there is little knowledge about the optimal dietary treatment. 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. To date however TRE has not been investigated in pregnant women.

Study objective

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 design

Admission, 4 weeks after admission and the last visit before expected delivery date

Intervention

All participants will receive standard care according to the current guidelines. The women in the TRE group will get the additional advice to restrict the daily period of food intake to a self-chosen 11- hr period. After 2 weeks they will further restrict food intake to a self-chosen 10-

hr period.

Contacts

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Scientific
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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.
- 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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	12-04-2021
Enrollment:	38
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	31-03-2021
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	NL9393
Other	METC AMC : METC 2019_259

Study results