

Time restricted eating to treat gestational diabetes mellitus

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We hypothesize that TRE improves insulin sensitivity, glucose values, and consequently neonatal and maternal outcomes in GDM, via strengthening of clock gene expression rhythms.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23529

Bron

Nationaal Trial Register

Verkorte titel

TRE-GDM

Aandoening

Gestational diabetes mellitus

Ondersteuning

Primaire sponsor: Amsterdam UMC

Overige ondersteuning: Asklepios foundation, Fonds Parkherstellingsoorden, Amsterdam Gastroenterology Endocrinology Metabolism research institute

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- average 2-hour postprandial glucose levels

- average fasting glucose levels

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

We hypothesize that TRE improves insulin sensitivity, glucose values, and consequently neonatal and maternal outcomes in GDM, via strengthening of clock gene expression rhythms.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Amsterdam UMC, location AMC
Dion Muller

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Wetenschappelijk

Amsterdam UMC, location AMC
Dion Muller

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind

Controle: Geneesmiddel

Deelname

Nederland

Status: Werving nog niet gestart

(Verwachte) startdatum: 12-04-2021

Aantal proefpersonen: 38

Type: Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum: 31-03-2021

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9393
Ander register	METC AMC : METC 2019_259

Resultaten