MYPP-trial: Myo-inositol Supplementation to Prevent Pregnancy Complications in Women with Polycystic Ovary Syndrome: a multicentre double-blind randomised controlled trial

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

Samenvatting

ID

NL-OMON28285

Bron
NTR

Verkorte titel
MYPP-trial

Aandoening

Polycystic ovary syndrome, Polycysteus ovarium syndroom, PCOS
Pregnancy complications, zwangerschapscomplicaties

Ondersteuning

Primaire sponsor: Erasmus MC, University Medical Center Rotterdam
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary endpoint will be the incidence of the composite outcome of either gestational diabetes mellitus, and/or preeclampsia and/or preterm birth (i.e. birth before 37 weeks gestational age).

Toelichting onderzoek

Achtergrond van het onderzoek

Polycystic Ovary Syndrome (PCOS) is the most common endocrine disorder in women of reproductive age. PCOS is a heterogeneous condition, characterised by metabolic disturbances, insulin resistance and hyperandrogenism. Pregnancies in women with PCOS have an increased risk of gestational diabetes mellitus, preeclampsia and preterm birth, and their offspring have an increased risk of aberrant birth weight and hospitalization. After pregnancy, PCOS is thought to have an impact on breastfeeding success and breastmilk composition.
Current strategies to improve pregnancy outcome among women with PCOS have not demonstrated significant risk reduction. Myo-inositol is a commonly used dietary supplement with a favourable effect on glucose metabolism and insulin sensitivity. Optimal intake of myo-inositol is associated with a decrease in glucose, lower insulin and lower testosterone levels in women with PCOS. Among women with PCOS-related disorders (e.g. in women with obesity), myo-inositol supplementation in pregnancy has been shown to have clinical benefits in preventing adverse pregnancy outcomes in a number of clinical trials, by reducing the risk of gestational diabetes mellitus, hypertensive complications and preterm birth.

The MYPP-trial will be the first randomised prospective trial aimed specifically at pregnant women with PCOS, to evaluate the potential effectiveness of myo-inositol supplementation as a nutritional intervention to prevent all three pregnancy complications associated with PCOS (i.e. GDM, preeclampsia and preterm birth). Secondary objectives are to evaluate the impact of supplementation on maternal (mental) and neonatal health, breastfeeding practices and breastmilk composition. In addition, a full cost-effectiveness analysis will be performed.
Women with a diagnosis of PCOS and a singleton pregnancy between 8+0 and 16+0 weeks of gestational age are eligible. Participants randomly allocated to the intervention group will receive 4 grams myo-inositol added to their routinely recommended folic acid supplement, divided over two daily sachets of sugary powder throughout pregnancy. The control group will receive similar looking sachets of supplements containing only the standard dose of folic acid without the added myo-inositol supplement, as part of the current standard-of-care recommendation. In addition to receiving supplements, participants will be asked to complete

three questionnaires, provide blood and urine samples once each trimester of pregnancy, and routine ultrasound scanning will be performed to assess fetal growth. All study visits will be aligned with routine antenatal care appointments. Additionally, subjects can choose to participate in research on the impact of myo-inositol supplementation on breastfeeding and take part in the MYPP biobank.
The results of this study will provide important novel recommendations for PCOS patients on the importance of optimising life-style and nutrient intake to improve pregnancy outcome.

Doel van het onderzoek

Based on previous clinical trials among pregnant women with PCOS-related disorders (e.g. in women with obesity) we expect daily intake of myo-inositol, as a safe nutritional intervention during pregnancy, will result in a 35% reduction in the composite outcome of GDM, preeclampsia and preterm birth among women with PCOS.

Onderzoeksopzet

Women with a diagnosis of PCOS will be included after confirmation of a viable singleton pregnancy by ultrasound between 8+0 and 16+0 weeks of gestational age.
After inclusion participants will be allocated at random to either the intervention group or the control group and will receive supplementation up until delivery. Participants will be followed-up until 6 weeks postpartum.
The primary outcome (i.e. the number of pregnancies complicated with either gestational diabetes, and/or preeclampsia and/or preterm birth) will be scored ultimately one week postpartum (as to include postpartum preeclampsia). Maternal and neonatal data will be collected until 6 weeks postpartum.
We will seek permission for follow-up of breastfeeding mothers until 6 months postpartum and seek permission for additional follow-up of children until school-age to monitor the long-term effects on development, metabolic changes and epigenetic changes (subject to additional protocols and funding).

Onderzoeksproduct en/of interventie

Participants randomly allocated to the intervention group will receive 4 grams myo-inositol added to their routinely recommended folic acid supplement, divided over two daily sachets of sugary powder throughout pregnancy. The control group will receive similar looking sachets of supplements containing only the standard dose of folic acid without the added myo-inositol supplement as part of the current standard-of-care recommendation.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- ≥ 18 years of age
- Diagnosis of PCOS according to the Rotterdam consensus criteria and confirmed by a gynaecologist
- A viable singleton pregnancy confirmed by ultrasound
- Being able to initiate the use of study supplements between 8+0 and 16+0 weeks gestational age
- Ability to understand Dutch or English
- Ability to provide written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Diagnosis of pre-existent type-1 or 2 diabetes mellitus
- Pre-existent renal failure, defined as an estimated glomerular filtration rate (eGFR) less than 50 ml/min/1.73m2
- Use of myo-inositol supplements, other insulin-mimetics, hypoglycaemic agents (e.g. metformin) and/or systemic steroids, that cannot be discontinued at the time of inclusion

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	17-06-2019
Aantal proefpersonen:	464
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
N/A

Ethische beoordeling

Positief advies

Datum:	16-06-2019
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	NL7799
Ander register	METC Erasmus MC : MEC-2019-0005, NL67329.078.18

Resultaten

Samenvatting resultaten
N/A