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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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Endocrine disorders of gonadal function
Study type	Interventional

Summary

ID

NL-OMON52766

Source
ToetsingOnline

Brief title
MYPP-trial

Condition

- Endocrine disorders of gonadal function
- Pregnancy, labour, delivery and postpartum conditions
- Gonadotrophin and sex hormone changes

Synonym
PCOS, polycystic ovary syndrome

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: myo-inositol, Polycystic Ovary Syndrome, Pregnancy Complications, prevention

Outcome measures

Primary outcome

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).

Secondary outcome

Secondary endpoints will include indicators of maternal physical and mental

well-being, maternal health-related quality of life, neonatal outcomes,

breastfeeding practices and breastmilk composition. In addition, a full

cost-effectiveness analysis will be performed.

Study description

Background summary

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. However, there are currently no prospective trials to evaluate the effect of myo-inositol supplementation as a nutritional intervention to prevent pregnancy complications among women with PCOS.

Study objective

The primary objective of this study is to assess the effectiveness of myo-inositol supplementation to prevent pregnancy complications in women with PCOS. Secondary objectives are to evaluate the impact of supplementation on maternal (mental) and neonatal health and assess cost-effectiveness.

Study design

Prospective multicentre, double-blind, randomised controlled trial.

Intervention

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.

Study burden and risks

Myo-inositol supplements have been used in several previous trials in pregnancy and is considered a safe food supplement without any side effects or risks. Myo-inositol is well tolerated at the amounts used in this study. 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 and blood tests. 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 prevent pregnancy complications.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

- >= 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

Exclusion criteria

- 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

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-06-2019
Enrollment:	464
Type:	Actual

Ethics review

Approved WMO

Date:	12-06-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	19-08-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	13-11-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-05-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	03-09-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-10-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	08-12-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-04-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL67329.078.18
Other	NL7799