Metformin vs Control to prevent gestational diabetes mellitus (GDM) in women with a high risk for GDM, an open label randomized controlled trial. The Medico-GDM trial.

Published: 01-04-2014
Last updated: 20-04-2024

The primary objective is to compare metformin versus no intervention for incidence of GDM in women with a high risk for GDM. The main secondary objective is pregnancy outcome with Metformin, neonatal outcomes and neonatal complications.

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

Summary

ID

NL-OMON41912

Source
ToetsingOnline

Brief title
Metformin to prevent gestational diabetes mellitus (GDM)

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Maternal complications of pregnancy

Synonym
diabetes that starts during pregnancy, Gestational diabetes mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Maasstad Ziekenhuis
Source(s) of monetary or material Support: Maasstad Ziekenhuis Vakgroep Interne Geneeskunde en Twiss fonds

Intervention

Keyword: (high risk for) gestational diabetes mellitus, Metformin, Prevention

Outcome measures

Primary outcome

The main study parameter is the difference in incidence of GDM between the two

groups.

Secondary outcome

Pregnancy outcome, neonatal outcome and neonatal complications

Study description

Background summary

GDM is a frequent pregnancy complication1 and associated with complications for mother and child.2 At present, the drug of choice for treatment of GDM is Insulin.3 In the last years several studies documented the use of oral blood glucose lowering medication in GDM. Metformin is an accepted alternative for insulin, with comparable glycemic control and neonatal outcomes.4
In studies with women with PCOS who received Metformin during pregnancy, the incidence of GDM is less compared to pregnant women with PCOS without Metformin. These studies were however small and there was no adequate control group.5 Our aim is to study the effect of Metformin on the incidence of GDM in women with a high risk for GDM.

Study objective

The primary objective is to compare metformin versus no intervention for incidence of GDM in women with a high risk for GDM. The main secondary objective is pregnancy outcome with Metformin, neonatal outcomes and neonatal

complications.

Study design

2 years open label randomized controlled trial, comparing metformin versus control group.

Intervention

All subjects will be instructed in a 2000 calories/day diet, with an adequate distribution of carbohydrates during the day. They receive a standard list of a diet they have to follow. It includes the quantity and the quality of the nutrition they have to take every day.
The first group receives Metformin twice daily 500 mg for the first week, after that twice daily 1000 mg. The second group receives no intervention.

Study burden and risks

The subjects will visit our centre for the first time between 12 and 14 weeks of pregnancy, then blood samples will be collected. Further on they will visit our centre at 24 weeks and 30 weeks to perform an OGTT. Women with GDM in history will perform an OGTT at 16 weeks for the first time. If the OGTT is borderline normal, it will repeated every 4 weeks. This is according to current Dutch guidelines3, without any extra discomfort for study participants. Metformin is not officially registered for use in pregnancy. Long term effects for the unborn child are not known. However, previous studies did not found neonatal and pregnancy related complications.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Women with a high risk for gestational diabetes mellitus
'High risk' is defined if one or more of the risk factors below is present, according to the Dutch national criteria for screening
- Gestational diabetes in history
- Body mass index > 30 (kg/m2) at the first prenatal screening
- Birth weight previous child > P95 or > 4500 gram
- First degree relative with diabetes mellitus
- Certain ethnic groups with a high prevalence of diabetes mellitus
(South Asians, like Hindustani, Afro-Caribbean people, women from the Middle East, Morocco and Egypt)
- History of unexplained intra-uterine foetal death/stillbirth
- Polycystic ovary syndrome (PCOS);And aged between 18 and 40 years, gestational age between 8 and 12 weeks, able to communicate and read in Dutch

Exclusion criteria

No singleton pregnancy judged by ultrasonography, high fasting glucose at first trimester, cardiac insufficiency, renal insufficiency (MDRD < 60), liver disease, use of medication other than Paracetamol or vitamins and incompetent women.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-10-2014
Enrollment:	400
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Metformin
Generic name:	Metformin
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	01-04-2014
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)
Approved WMO Date:	23-07-2014
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)
Approved WMO Date:	23-12-2014

Application type:	Amendment
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)
Approved WMO Date:	25-02-2015
Application type:	Amendment
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)
Approved WMO Date:	25-03-2015
Application type:	Amendment
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (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
EudraCT	EUCTR2014-000446-30-NL
CCMO	NL48005.101.14

Study results

Date completed:	22-03-2017
Actual enrolment:	51