TANGO-DM: Randomized trial of effective treatment according to new GDM criteria

Published: 14-08-2018
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To evaluate the effectiveness and cost-effectiveness of intensive GDM treatment as compared to routine maternity care in pregnant women with a discordant OGTT result between the new (2013) WHO criteria as compared to the old (1999) WHO criteria for...

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

Summary

ID

NL-OMON52951

Source
ToetsingOnline

Brief title
TANGO-DM

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Pregnancy, labour, delivery and postpartum conditions

Synonym
diabetes in pregnancy, GDM, gestational diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Leading the Change

Intervention

Keyword: diagnostic criteria, gestational diabetes, threshold

Outcome measures

Primary outcome

The primary outcome will be the incidence of birth weight >90th centile (LGA).

Secondary outcome

Secondary outcomes include mode of delivery (caesarean sections), maternal outcomes, perinatal outcomes including perinatal mortality, gestational age at delivery, shoulder dystocia, birth trauma, neonatal hypoglycaemia, neonatal intensive care admission, need for phototherapy, quality of life and societal costs.

Study description

Background summary

Gestational diabetes mellitus (GDM), defined as hyperglycemia in pregnancy, is currently diagnosed in approximately 5% of all pregnancies. GDM carries significant perinatal risks including large-for-gestational-age (LGA) infants, shoulder dystocia, preeclampsia, caesarean section, and neonatal hypoglycemia. There is a gradual increase in adverse perinatal outcomes with increasing maternal glycemia at oral glucose tolerance testing (OGTT). The new (2013) WHO criteria propose to lower the fasting threshold for GDM diagnosis in comparison to the old (1999) WHO criteria. It is unclear whether this will lead to improved perinatal outcomes for this group of women with GDM. We hypothesize that intensive GDM treatment of women according to the new (2013) GDM criteria who were considered normal in the old criteria, will result in a reduction in infants with birth weight >90th centile (large for gestational age, LGA) at acceptable costs, in comparison to the old criteria.

Study objective

To evaluate the effectiveness and cost-effectiveness of intensive GDM treatment as compared to routine maternity care in pregnant women with a discordant OGTT

result between the new (2013) WHO criteria as compared to the old (1999) WHO criteria for gestational diabetes mellitus.

Study design

Multicentre open-label randomized controlled trial (RCT).

Intervention

The intervention is intensive GDM treatment, including monitoring of blood glucose values, dietary recommendations and pharmacotherapy for those unable to achieve euglycemia with dietary intervention alone. The comparison will be routine maternity care.

Study burden and risks

Burden: All participants will be asked to complete a questionnaire on 3 occasions (10-35 minutes per questionnaire). In addition to usual maternity care, participants allocated to intensive treatment will have additional appointments for personalized dietary advice, and will if needed be referred to a diabetes nurse or an endocrinologist. It is more likely that they will be referred to the obstetrician and that induction of labour before term will be discussed. Intensive treatment also includes recording blood glucose levels several times a day (finger stick measure), weight and (if necessary) medication.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

- Singleton pregnancy
- Aged >18 years
- OGTT for all indications
- OGTT conducted between gestational ages 16+0 and 30+ 0 weeks
- Discordant result on a 3-point 75-gram OGTT i.e.:
o Fasting glucose > 5.1 and <7.0 mmol/l OR
o 1-hour glucose >=10.0 mmol/l OR
o 2-hour glucose >7.8 and <8.4 mmol/l
- Gestational age <32+0 at study inclusion

Exclusion criteria

- known preconception diabetes
- major fetal congenital /chromosomal abnormality (eg trisomy 21, spina bifida), known at time of randomization
- significant medical or psychiatric co-morbidities as judged by the investigator (e.g. high dose corticosteroid treatment)
- inability to understand written informed consent without help as indicated by their usual care provider

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	04-10-2018
Enrollment:	1032
Type:	Actual

Ethics review

Approved WMO Date:	14-08-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-11-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-11-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-03-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-05-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-07-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	27-08-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-10-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-04-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-02-2024
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 23396
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL63013.018.18