Treatment outcomes for gestational diabetes diagnosed either according to WHO 2013 or WHO 1999 thresholds: the TANGO-DM Randomized Controlled Trial

Published: 06-09-2018
Last updated: 14-09-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Maternal complications of pregnancy
Study type	Interventional

Summary

ID

NL-OMON23396

Source
Nationaal Trial Register

Brief title
TANGO-DM

Condition

- Maternal complications of pregnancy

Health condition

GDM Diabetes gravidarum Gestational diabetes zwangerschapsdiabetes

Research involving
Fetus in utero, Human

Sponsors and support

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

Intervention

- Food (substances)

Explanation

Outcome measures

Primary outcome

Large for gestational age (LGA, defined as birth weight >90th centile, using the Dutch Perined reference charts)

Secondary outcome

Secondary perinatal outcomes will include:
• Perinatal mortality (up until 6 weeks postpartum)
• Birth weight
• Birth weight >4000 g
• Small for gestational age (• Gestational age at delivery
• Preterm delivery (<37 weeks)
• Reason for preterm delivery (iatrogenic, spontaneous)
• 1-min Apgar score
• 5-min Apgar score
• 10-min Apgar score
• Shoulder dystocia
• Birth injury (i.e. fractures, nerve palsy)
• Cord blood C peptide (in a subset, where available)
• Neonatal glucose postpartum: 1-3-6-12-24 hours or similar (in GDM treatment group) • Neonatal hypoglycaemia (moderate, serum glucose <2.6 mmol/l; severe, serum glucose <2.0 mmol/l)
• Neonatal intensive care/medium care admission
• Hyperbilirubinemia necessitating phototherapy
• Respiratory support > 24 hours
• Neonatal encephalopathy

Secondary outcomes of delivery:
• Mode of delivery (spontaneous, assisted vaginal, caesarean). We will split instrumental deliveries for fetal distress or non-progressive labour
• Induction of labour
• Post-partum haemorrhage

Secondary maternal outcomes will include:
• Hypertensive disorders of pregnancy (including preeclampsia and pregnancy induced hypertension)
• Need for treatment with insulin or oral glucose lowering medication
• Maternal total weight gain in gestation
• Glycemic control: diary (in GDM treatment group)
• Puerperal sepsis requiring antibiotics
• Maternal admission postpartum
• Serious health outcomes up to the time of primary hospital discharge assessed from patient medical records23.
• Intention to breastfeed prior to giving birth
• Breastfeeding at the end of postpartum period
Cost effectiveness analysis:
• Societal costs
• Quality-adjusted life years
Both from a societal and healthcare perspective

Study description

Background summary

Gestational diabetes mellitus (GDM), or hyperglycemia first diagnosed in pregnancy, affects 7-10% of all pregnancies worldwide. Perinatal risk rises with increasing glycemia at oral glucose tolerance test (OGTT). The new (2013) WHO criteria recommend a lower fasting, and a higher post-load threshold for GDM diagnosis in comparison to the old (1999) WHO criteria. To date, however, outcomes of GDM treatment for those affected by the altered diagnostic criteria, has not been well investigated.

Study objective

We hypothesized that intensive GDM treatment according to the new (2013) GDM criteria would result in a reduction in infants with birth weight >90th centile (large for gestational age, LGA), in comparison to treatment according to the old criteria (1999).

Study design

Multicentre open-label randomized controlled trial (RCT).

Intervention

The intervention under investigation will be intensive GDM treatment of women with OGTT results discordant between the new and the old criteria. Treatment will comply with the NVOG guideline: monitoring of blood glucose, dietary recommendations and pharmacotherapy for those unable to achieve euglycemia with dietary intervention alone.

The comparator will be routine obstetric care.

Contacts

Public

Scientific

Eligibility criteria

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

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 ¡Ý10.0 mmol/l OR
o 2-hour glucose >7.8 and <8.4 mmol/l
- Gestational age <32+0 at study inclusion
- Written informed consent

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 phase:	N/A
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown
Primary purpose:	Diagnostic

Recruitment

NL

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

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Approved WMO

Date:	16-08-2018
Application type:	First submission
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389

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Study registrations

Followed up by the following (possibly more current) registration

ID: 52951
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7127
NTR-old	NTR7473
CCMO	NL63013.018.18
OMON	NL-OMON52951

Study results