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Impact on pregnancy outcomes when changing diagnostic criteria for gestational diabetes in Sweden

Submission date
27/11/2017

Recruitment status
No longer recruiting

Registration date
15/12/2017

Overall study status
Ongoing

Last Edited
09/07/2024

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Gestational diabetes mellitus (GDM) is high blood sugar that develops during pregnancy. In June 2015, the Swedish National Board of Health reviewed the evidence on the current Swedish and WHO GDM criteria and recommended adoption of the new, stricter WHO diagnostic criteria for what is considered GDM. GDM is currently being treated differently in different hospitals /regions and the care is not equal. It is unknown if the change of the diagnostic criteria will lead to any benefits in Sweden. The new criteria mean a major change in the number of pregnant women who gets diagnosed (estimated a triple increase based on studies in other countries). The CDC4G study is a randomized national multicenter study to evaluate the Swedish National Board of Health's new recommendation for gestational diabetes mellitus (GDM) diagnostic criteria in Sweden. The new diagnostic criteria will be compared to the old criterions used in Sweden. The aim of this study is to examine if treating women with GDM defined by the new criteria will reduce risks of adverse pregnancy outcomes in the Swedish population.

Who can participate?
Pregnant woman in the maternity hospitals.

What does the study involve?
Participating hospitals are randomly allocated to when they switch from the pre-existing Swedish diagnostic criteria for GDM to the WHO 2013 criteria for GDM to the 3 point OGTT with fasting, one hour and/or two hour diagnostic thresholds. Participants are followed up to assess if their babies are large for their gestation age, if they develop hypertension, pre-eclampsia or any other complications at labour.

What are the possible benefits and risks of participating?
The expected outcome is a significant reduction in the proportion of large children and complications related to this during childbirth. Follow-up of mothers, children and their long-term health will be performed through the national health and quality records.
The results of the study are expected to be of great significance for the clinics that treats pregnant women with diabetes. Hopefully it will also lead to a more equal care for when it

comes to GDM and for the future pregnant individual, no matter where in Sweden they might live.

Where is the study run from?
This study is being run by the University Hospital Örebro (Sweden) and takes place in hospitals in Sweden.

When is the study starting and how long is it expected to run for?
October 2015 to December 2025

Who is funding the study?
Region Örebro County (Sweden)

Who is the main contact?
Dr Helena Backman

Study website
http://www.cdc4g.com

Contact information

Type(s)
Scientific

Contact name
Dr Helena Backman

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Contact details
Dept of Obstetrics and Gynecology
University Hospital Örebro
Örebro
Sweden
70185

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
OLL-597601

Study information

Scientific Title
Impact of Changing Diagnostic criteria for Gestional diabetes in Sweden - a national stepped wedge randomized controlled trial

Acronym
CDC4G

Study objectives
1. Treating women with GDM defined by the new criteria will reduce risks of adverse pregnancy outcomes in the Swedish population.
2. the new criteria will be cost effective. Even though there will be more costs in obstetrics, reduced costs will be seen in neonatal care and probably later on in primary health care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethical Committee in Uppsala County, 2016/12/07, ref: Dnr2016/487

Study design
National multicenter unblinded interventional study with a stepped wedge randomized controlled design

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
No participant information sheet available.

Health condition(s) or problem(s) studied
Gestational diabetes mellitus

Interventions
The intervention is the switch from the pre-existing Swedish diagnostic criteria to the WHO 2013 criteria for GDM to the 3 point OGTT with fasting, 1 hour and/or 2 hour diagnostic thresholds of ≥5.1, ≥10.0, ≥8.5 mmol/l. This stepped wedge randomised controlled study design allows each participating center (cluster) to be their own controls before and after randomization. All eligible women from the participating centres are randomised for starting time to the new regime. Randomisation is done through a RCT module from the Pregnancy Register.

Intervention Type

Other

Primary outcome measure

Large for Gestational Age (LGA) is measured as the weight of the baby will be measured at time of birth.

Secondary outcome measures

Current secondary outcome measures as of 28/02/2019 in accordance with approved ethical protocol from 07/12/2016:
1. Composite of severe adverse outcomes (stillbirth, neonatal death, Erbs palsy, metabolic acidosis defined as pH <7.05 and BE >12 mmol/l in umbilical artery or pH <7.0 in umbilical artery, Apgar score <4 at 5 minutes, HIE I-III, intracranial haemorrhage, neonatal convulsions, meconium aspiration syndrome, mechanical ventilation)
2. 5-Min Apgar score <7
3. Fractured clavicle
4. Blood glucose in the infants
5. Prematurity <37 weeks
6. NICU admission yes/no
7. NICU days
8. Small for Gestational Age
9. Health economic outcome
10. Incremental Cost Effectiveness Ratio
11. Hypoglycaemia needing IV therapy
12. Phototherapy
13. Blood glucose in the infants

Maternal outcomes:
1. Hypertension, Pre-eclampsia-defined is measured using blood pressure and proteinuria at labour and/or discharge
2. Shoulder dystocia is measured using pregnancy quality register (Shoulder dystocia ICD O660) at labour and/or discharge
3. Perineal trauma-3 and 4 degree measured using pregnancy quality register (Perineal trauma ICD O70) at labour and/or discharge
4. Induction of labour is measured using medical records at labour
5. Breastfeeding at hospital discharge
6. Emergency C-section is measured using medical records at labour and/or discharge
7. Elective C-section is measured using medical records at labour and/or discharge
8. Instrumental delivery is recorded using medical records at labour and/or discharge
9. Length of maternal postnatal stay is recorded using medical records at discharge

Previous secondary outcome measures:
1. Hypertension, Pre-eclampsia-defined is measured using blood pressure and proteinuria at labour and/or discharge
2. Shoulder dystocia is measured using pregnancy quality register (Shoulder dystocia ICD O660) at labour and/or discharge
3. Perineal trauma-3 and 4 degree measured using pregnancy quality register (Perineal trauma ICD O70) at labour and/or discharge
4. Induction of labour is measured using medical records at labour
5. Breastfeeding at hospital discharge
6. Emergency C-section is measured using medical records at labour and/or discharge
7. Elective C-section is measured using medical records at labour and/or discharge

8. Instrumental delivery is recorded using medical records at labour and/or discharge
9. Length of maternal postnatal stay is recorded using medical records at discharge

Overall study start date
01/10/2015

Completion date
31/12/2025

Eligibility

Key inclusion criteria
All pregnant women in the participating hospitals and their uptake regions.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
12 clusters, total sample size of 71 500 pregnant women (35750 before change and 35750 after change of the new GDM criteria).

Key exclusion criteria
Preexisting diabetes mellitus.

Date of first enrolment
01/01/2018

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
Sweden

Study participating centre
University Hospital Örebro
Örebro
Sweden
701 85

Study participating centre
Sahlgrenska University Hospital
Västra Götaland County
Gothenburg
Sweden
41685

Study participating centre
Falun Regional Hospital
Dalarna County
Falun
Sweden
79185

Study participating centre
Uppsala academy Hospital
Uppsala county
Uppsala
Sweden
75375

Study participating centre
Västerås Hospital
Västmanland County
Västerås
Sweden
72187

Study participating centre
Serafen Maternal Health Care Unit
Stockholm County
Stockholm
Sweden
10535

Study participating centre
Gotland Hopsital
Gotland County

Gotland
Sweden
62266

Study participating centre
Skåne University Hospital
Skåne county
Lund
Sweden
22242

Study participating centre
Skåne University Hospital
Malmö
Sweden
21428

Study participating centre
Kristianstad Hospital
J A Hedlunds väg 5
Kristianstad
Sweden
291 33

Study participating centre
Varberg Hospital
Träslövsvägen 68
Varberg
Sweden
43281

Study participating centre
Kungsbacka Hospital
Tölö vägen
Kungsbacka
Sweden
43480

Sponsor information

Organisation
Region Örebro County

Sponsor details
Box 161
Örebro
Sweden
70185

Sponsor type
Hospital/treatment centre

Website
www.regionorebolan.se

ROR
https://ror.org/00maqj547

Funder(s)

Funder type
Government

Funder Name
Region Örebro County

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer reviewed journal. Study protocol will be submitted and published after the last clinic has been randomized fall 2018.

Intention to publish date
30/09/2023

Individual participant data (IPD) sharing plan
Data can be shared based on the decision of the steering group for CDC4G and according to local regulations and laws.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/11/2019	06/11/2019	Yes	No
Statistical Analysis Plan	version 8	28/10/2022	19/12/2022	No	No
Statistical Analysis Plan	Corrections	12/05/2023	12/05/2023	No	No
Results article		08/07/2024	09/07/2024	Yes	No