

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

Submission date 27/11/2017	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 15/12/2017	Overall study status Completed	☒ Statistical analysis plan ☒ Results
Last Edited 09/07/2024	Condition category Pregnancy and Childbirth	☐ 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

Contact information

Type(s)

Scientific

Contact name

Dr Helena Backman

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Contact details

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University Hospital Örebro

Örebro

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70185

Additional identifiers

Protocol serial number

OLL-597601

Study information

Scientific Title

Impact of Changing Diagnostic criteria for Gestational 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

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s))

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

Completion date

31/12/2025

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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 Hospital
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

ROR

<https://ror.org/00maqj547>

Funder(s)

Funder type

Government

Funder Name

Region Örebro County

Results and Publications

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?
Results article		08/07/2024	09/07/2024	Yes	No
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
Study website	Study website	11/11/2025	11/11/2025	No	Yes