

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

<b>Submission date</b> 27/11/2017	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 15/12/2017	<b>Overall study status</b> Ongoing	<input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/07/2024	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> 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

**ORCID ID**

<http://orcid.org/0000-0002-2691-7525>

**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 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

**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  $\geq 5.1$ ,  $\geq 10.0$ ,  $\geq 8.5$  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](http://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?
<a href="#">Protocol article</a>	protocol	01/11/2019	06/11/2019	Yes	No
<a href="#">Statistical Analysis Plan</a>	version 8	28/10/2022	19/12/2022	No	No
<a href="#">Statistical Analysis Plan</a>	Corrections	12/05/2023	12/05/2023	No	No
<a href="#">Results article</a>		08/07/2024	09/07/2024	Yes	No