

# Modified antenatal care for healthy pregnant women with low risk for adverse outcomes

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| <b>Submission date</b><br>15/03/2021   | <b>Recruitment status</b><br>No longer recruiting     | <input type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>21/04/2021 | <b>Overall study status</b><br>Ongoing                | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                                  |
| <b>Last Edited</b><br>14/04/2025       | <b>Condition category</b><br>Pregnancy and Childbirth | <input type="checkbox"/> Individual participant data<br><input checked="" type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

The standard antenatal care (SAC) program in Sweden is optional, free of charge with a high attendance rate of almost 100%.

A modified antenatal care program (MAC) to pregnant women with low risks supports distributing resources to those who need them most. The proportion of women with moderate or high risk for complications during pregnancy and childbirth giving birth nowadays is increasing due to e.g. obesity, advanced age or diseases. It is therefore important to individualize the antenatal visits to a higher extent and make possibilities for those women that are in need of more visits with the midwives.

### Who can participate?

All healthy pregnant women aged 18 years and over defined as low risk

### What does the study involve?

Participants will be allocated to the SAC or the MAC program.

The SAC program (visits to a midwife in gestational week 6-10, 12-15, 25, 29, 32, 35, 37, 39, 41) will be compared with the MAC program (visits to a midwife in gestational week 6-10, 12-15, 29,35,38 and video meetings in gestational week 25, 40).

### What are the possible benefits and risks of participating?

No additional risks or benefits

### Where is the study run from?

Department of Obstetrics and Gynecology and Department of Biomedical and Clinical Sciences, Linköping University, Linköping, Sweden

### When is the study starting and how long is it expected to run for?

October 2019 to October 2026

### Who is funding the study?

Medical Research Council of Southeast Sweden FORSS-939956

Who is the main contact?

Dr Caroline Lilliecreutz, caroline.lilliecreutz@regionostergotland.se

## Contact information

### Type(s)

Scientific

### Contact name

Dr Caroline Lilliecreutz

### ORCID ID

<https://orcid.org/0000-0001-9491-9728>

### Contact details

Womens Clinic floor 14

University Hospital

Linköping

Sweden

58185

+46 101033160

caroline.lilliecreutz@regionostergotland.se

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Protocol serial number

Nil known

## Study information

### Scientific Title

Modified antenatal care (MAC) program for healthy pregnant women with low risk for adverse outcomes – a stepped wedge cluster noninferiority randomised trial

### Acronym

MAC-study

### Study objectives

1. The modified antenatal care (MAC) program has not more negative maternal and fetal outcomes than the present standard antenatal care (SAC) program.
2. The modified antenatal care (MAC) program has not more negative patient related experience measurement (PREM) outcomes than the present standard antenatal care (SAC) program.

### Ethics approval required

Old ethics approval format

## **Ethics approval(s)**

1. Approved 29/11/2020, Stockholm avdelning 2 medicin (Box 2110, Uppsala, 75002 Uppsala, Sweden; +46 (0)10-4750800; [registrator@etikprovning.se](mailto:registrator@etikprovning.se)), ref: Dnr 2022-06144-02
2. Approved 29/11/2022, Stockholm avdelning 2 medicin (Stockholm avdelning 2 medicin, Stockholm, Stockholm avdelning 2 medicin, Sweden; Stockholm avdelning 2 medicin; [registrator@etikprovning.se](mailto:registrator@etikprovning.se)), ref: Dnr 2022-06144-02

## **Study design**

Interventional cluster randomized trial

## **Primary study design**

Interventional

## **Study type(s)**

Prevention

## **Health condition(s) or problem(s) studied**

Antenatal care for healthy pregnant women with low risk for complications

## **Interventions**

This is a noninferiority trial with the aim to determine if the MAC program does not differ in quality and safety compared with the SAC program in terms of maternal and neonatal outcome. The stepped wedge randomised controlled design is mainly used to evaluate the clinical routine implementation and therefore chosen for this study. All sites (clusters) are in the end adopting the MAC program.

A modified antenatal care program for healthy pregnant women with low-risk för complications with 4 inhouse visits, 2 ultrasounds and 2 digital meetings will be compared with the standard care program with 8 in house visits and 2 ultrasounds. At the beginning of the study, all 3 clusters will adopt the same standard care program and in the end, all 3 clusters will adopt the modified care program.

The duration of the programs is around 42 weeks.

## **Intervention Type**

Mixed

## **Primary outcome(s)**

Intrauterine growth restriction during pregnancy (yes/no) collected from the Swedish Pregnancy Register and from reviewing patients medical records after recruitment

## **Key secondary outcome(s)**

Collected from the Swedish Pregnancy Register and from reviewing patients medical records after recruitment:

1. Number of visits to the antenatal care clinic
2. Number of video meetings
3. Number of visits to the delivery unit
4. Number of midwives involved during the antenatal care
5. Number of inpatient care admissions
6. Pregnancy-induced Hypertension
7. Preeclampsia

8. Eclampsia
9. Breastfeeding at 4 weeks and 6 months
10. Participation in-group education during pregnancy Smoking during pregnancy
11. Number of women with recommended weight gain during pregnancy
12. Treatment of Fear of childbirth
13. Treatment of mental ill-health
14. Symptoms of postpartum depression 2 months after childbirth
15. Induction of labour
16. Number of vaginal, vacuum or caesarean deliveries
17. Number of pregnant women who had to change program due to higher risk complications or for other reasons
18. Intrauterin fetal death
19. Small for gestational age
20. Large for gestational age
21. Gestational week at childbirth
22. Admission to neonatal intensive care unit
23. Apgar < 4 at 5 minutes
24. PREM: expectations, fulfilment of expectations, accessibility, communication, information, sense of security, participation, support, overall satisfaction measured using a questionnaire in gestational week 38.

**Completion date**

01/10/2026

## **Eligibility**

**Key inclusion criteria**

All healthy pregnant women defined as low risk

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

Female

**Total final enrolment**

5374

**Key exclusion criteria**

Does not meet the inclusion criteria

**Date of first enrolment**

01/10/2020

**Date of final enrolment**

01/10/2023

## Locations

**Countries of recruitment**

Sweden

**Study participating centre****Linköping University Hospital**

Department of Obstetrics and Gynecology and Department of Biomedical and Clinical Sciences

Linköping

Sweden

58185

## Sponsor information

**Organisation**

Medical Research Council of Southeast Sweden

## Funder(s)

**Funder type**

Government

**Funder Name**

Forskningsrådet i Sydöstra Sverige

**Alternative Name(s)**

Medical Research Council of Southeast Sweden, FORSS

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Local government

**Location**

Sweden

# Results and Publications

## Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date.

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

| Output type                      | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|----------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Protocol article</a> |         | 08/04/2022   | 11/04/2022 | Yes            | No              |