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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
15/03/2021		[X] Protocol		
Registration date	Overall study status Ongoing Condition category Pregnancy and Childbirth	Statistical analysis plan		
21/04/2021		Results		
Last Edited		Individual participant data		
14/04/2025		[X] 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

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

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), 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), 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?
<u>Protocol article</u>	Participant information sheet	08/04/2022	11/04/2022	Yes	No
Participant information sheet		11/11/2025	11/11/2025	No	Yes