ISRCTN14422582 https://doi.org/10.1186/ISRCTN14422582

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

Submission date
15/03/2021

Recruitment status
No longer recruiting

Registration date
21/04/2021

Overall study status
Ongoing

Last Edited
14/04/2025

Condition category
Pregnancy and Childbirth

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

Who is the main contact?
Dr Caroline Lilliecreutz, caroline.lilliecreutz@regionostergotland.se

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
No participant information sheet available

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

Secondary outcome measures
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.

Overall study start date
01/10/2019

Completion date
01/10/2026

Eligibility

Key inclusion criteria
All healthy pregnant women defined as low risk

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
3 clusters with approx 1,800, 1,980 and 720 patients each

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
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Sponsor information

Organisation
Medical Research Council of Southeast Sweden

Sponsor details

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Sponsor type
Research council

Website
https://www.researchweb.org/is/en/forss

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/10/2026

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?
Protocol article		08/04/2022	11/04/2022	Yes	No