

Treatment with aspirin for recurrent abortion

Submission date 22/09/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/11/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 21/08/2019	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Treatment with acetylsalicylic acid for idiopathic recurrent abortion: a randomised trial

Acronym

RECAB-ASA

Study objectives

Hypercoagulability may increase the risk of microthrombosis in spiral arteries in early pregnancy, which may contribute to the risk of early pregnancy loss. Counteraction with anticoagulants such as acetylsalicylic acid (ASA) would reduce the risk of thrombosis and hence the risk of miscarriage in patients with idiopathic recurrent abortion.

The null hypothesis is that there is no difference in birth rate in women with idiopathic recurrent abortion if treated with low-dose ASA during pregnancy compared with women treated with placebo. The alternative hypothesis is that there is a higher birth rate in patients treated with low-dose ASA compared with placebo.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Regional Board of Ethics Approval at University of Gothenburg approved on the 7th August 2007 (ref: 234-07)

Study design

Randomised double-blind placebo-controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet (Swedish only)

Health condition(s) or problem(s) studied

Idiopathic recurrent abortion

Interventions

ASA 75 mg, taken orally, given between gestational weeks 6 - 36. Controls are given placebo pills. Follow-up is until the pregnancy has ended, either as a miscarriage or as a delivery. Follow-up will end when the patient is discharged from hospital in case hospital ward was needed, as after delivery.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Acetylsalicylic acid

Primary outcome measure

Live birth at at least 24 gestational weeks

Secondary outcome measures

1. Miscarriage, recorded when they occur, as patients report or at specified controls at gestational weeks 9, 12, 20, 30 and 36
2. Vaginal bleeding, recorded when they occur, as patients report or at specified controls at gestational weeks 9, 12, 20, 30 and 36
3. Placenta praevia, recorded when they occur, as patients report or at specified controls at gestational weeks 9, 12, 20, 30 and 36
4. Premature delivery, measured in hospital at or after delivery
5. Intrauterine growth retardation, measured until discharge from hospital after delivery
6. Pre-eclampsia, recorded when they occur, as patients report or at specified controls at gestational weeks 9, 12, 20, 30 and 36
7. Perinatal mortality, measured until discharge from hospital after delivery
8. Perinatal morbidity, measured as Apgar score and days in neonatal intensive care unit, measured until discharge from hospital after delivery

Overall study start date

01/01/2008

Completion date

01/01/2012

Eligibility**Key inclusion criteria**

1. Female participants aged 18 - 38 years
2. Idiopathic recurrent abortion, defined as at least three miscarriages between gestational weeks 6 - 12 within the same relationship. One full term pregnancy can be included.
3. Work-up according to the study protocol without a positive finding

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

38 Years

Sex

Female

Target number of participants

400

Total final enrolment

400

Key exclusion criteria

1. Allergy to ASA
2. Previous participation in the study
3. Age above 37 years
4. Body mass index (BMI) above 35 kg/m²
5. Positive findings in the work-up, requiring specific treatment for recurrent abortion
6. Concurrent treatment with ASA for other condition

Date of first enrolment

01/01/2008

Date of final enrolment

01/01/2012

Locations**Countries of recruitment**

Sweden

Study participating centre

Department of Obstetrics and Gynaecology

Borås

Sweden

501 82

Sponsor information**Organisation**

Södra Älvsborgs Hospital (Södra Älvsborgs Sjukhus) (Sweden)

Sponsor details

Department of Obstetrics and Gynaecology

Borås

Sweden
501 82

Sponsor type

Hospital/treatment centre

Website

<http://sas.vgregion.se/>

ROR

<https://ror.org/01qas6g18>

Funder(s)

Funder type

Government

Funder Name

Regional Research Unit of Western Sweden (Sweden) (ref: VGFOUREG-12231; Diarienr. VGFOUREG-27421)

Funder Name

Local Research Unit of Södra Älvsborgs (Sweden) (ref: VGFOUSA-10100; VGFOUSA-10114; VGFOUSA-38131)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2018	21/08/2019	Yes	No