

# Treatment with aspirin for recurrent abortion

<b>Submission date</b> 22/09/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/11/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 21/08/2019	<b>Condition category</b> 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

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## Additional identifiers

**Protocol serial number**  
N/A

## Study information

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

**Acronym**  
RE CAB-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**

Intentional

## **Study type(s)**

Treatment

## **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(s)**

Live birth at at least 24 gestational weeks

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

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

38 years

**Sex**

Female

**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/m<sup>2</sup>
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)

**ROR**

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

## Funder(s)

**Funder type**

Government

**Funder Name**

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

**Funder Name**

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

## Results and Publications

### 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?
<a href="#">Results article</a>	results	01/11/2018	21/08/2019	Yes	No