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Treatment with aspirin for recurrent abortion

Submission date 22/09/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/11/2009	**Overall study status** Completed	
Last Edited 21/08/2019	**Condition category** Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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/m^2
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