Antiphospholipid syndrome in pregnancy: A controlled treatment trial

Submission date	Recruitment status No longer recruiting	Prospectively registered		
23/01/2004		☐ Protocol		
Registration date 23/01/2004	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
12/01/2010	Pregnancy and Childbirth			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number RHC18084

Study information

Scientific Title

Study objectives

To assess the efficacy of low dose heparin in the treatment of antiphospholipid antibody syndrome during pregnancy, comparing low dose aspirin with low dose aspirin combined with low molecular weight heparin, in women suffering from recurring pregnancy loss.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Pregnancy; antiphospholipid antibody syndrome

Interventions

- 1. Aspirin
- 2. Aspirin and low molecular weight heparin

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Live birth rate in both arms of the trial (defined as the live birth rate after 24 weeks gestation).

Key secondary outcome(s))

The secondary outcome measures will concern maternal morbidity, e.g. osteoporosis, and fetal parameters, such as premature delivery and the incidence for "small for dates".

Completion date

01/01/2000

Eligibility

Key inclusion criteria

Pregnant women with antiphospholipid antibody syndrome

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

01/01/1998

Date of final enrolment

01/01/2000

Locations

Countries of recruitment

United Kingdom

England

Study participating centre Liverpool Women's Hospital

Liverpool United Kingdom L8 7SS

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

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?
Results article	results	01/09/2002		Yes	No