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Antiphospholipid syndrome in pregnancy: A controlled treatment trial

Submission date	Recruitment status	[ ] Prospectively registered
23/01/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/01/2004	Completed	[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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

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

Secondary outcome measures

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".

Overall study start date
01/01/1998

Completion date
01/01/2000

Eligibility

Key inclusion criteria
Pregnant women with antiphospholipid antibody syndrome

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
98 (added 12/01/10; see publication)

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
England

United Kingdom

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)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive North West (UK)

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	01/09/2002		Yes	No