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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

**Contact name**
Dr Roy Farquharson

**Contact details**
Liverpool Women's Hospital
Crown Street
Liverpool
United Kingdom
L8 7SS
+44 (0)151 708 9988
Roy.Farquharson@lwh-tr.nwest.nhs.uk

## 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 |