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# Pilot study of a randomised controlled trial of antenatal thromboprophylaxis

| 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 |
| 17/02/2010 | 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**
N/A

# Study information

### Scientific Title

### Acronym
APPLE

### Study objectives
In many hospitals, pregnant women who are at risk of developing thromboembolic disease (TED) are given thromboprophylaxis using heparin, despite the fact that there is no good quality evidence from randomized control trials (RCT) that this therapy is effective. Moreover, heparin can cause serious side effects, especially osteoporosis. The risks of side effects are unknown, and it is possible that thromboprophylaxis may cause more harm then good. RCTs are necessary to evaluate without bias the risks and benefits of this therapy.

### 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 and childbirth: thromboembolic disease (TED)

### Interventions
Heparin vs placebo

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome measure
Incidence of thromboembolic disease and side effects (especially osteoporosis) will be recorded

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
01/08/1999

### Completion date
01/02/2002

## Eligibility

### Key inclusion criteria
Pregnant women who are at risk of developing thromboembolic disease (TED)

### Participant type(s)
Patient

### Age group
Adult

### Sex
Female

### Target number of participants
16

### Key exclusion criteria
1. Women are known to have a thrombophillia sensitivity
2. Have had more than one previous episode of TED
3. Are known to have heparin sensitivity
4. Have had a previous cerebral venous thrombosis
5. Are receiving long term anticoagulant therapy

### Date of first enrolment
01/08/1999

### Date of final enrolment
01/02/2002

## Locations

### Countries of recruitment
England

United Kingdom

**Study participating centre**
**National Perinatal Epidemiology Unit**
Oxford
United Kingdom
OX3 7LF

# 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 South East (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 | 01/10/2004 | | Yes | No |