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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

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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Prevention

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(s)
Incidence of thromboembolic disease and side effects (especially osteoporosis) will be recorded

Key secondary outcome(s)
Not provided at time of registration

Completion date
01/02/2002

Eligibility

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

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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
United Kingdom

England

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)

Funder(s)

Funder type
Government

Funder Name
NHS Executive South East (UK)

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	01/10/2004		Yes	No