Two studies of blood pressure (BP) elevation associated with pregnancy and the oral contraceptive

Submission date	Recruitment status	Prospectively registered
12/09/2003	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
12/09/2003	Completed	Results
Last Edited	Condition category	Individual participant data
08/06/2017	Circulatory System	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number N0241048443

Study information

Scientific Title

Two studies of blood pressure (BP) elevation associated with pregnancy and the oral contraceptive

Study objectives

- 1. Do combined oral contraceptives (COC) exert a differential effect on the blood pressures (BP) of women with and without a past history of BP elevation in pregnancy?
- 2. Do oral progestrogen only contraceptives produce a significant elevation of BP in women who have had COC-induced hypertension?

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)

Treatment

Health condition(s) or problem(s) studied

Cardiovascular: Hypertension

Interventions

Study 1 (controlled trial):

25 women who have developed significant BP elevation during pregnancy and 25 who have never suffered raised BP during pregnancy will receive combined oral contraceptives.

Study 2 (randomised controlled trial):

50 women with a history of raised BP in association with taking oral contraceptives will be randomised to receive a progestrogen-only contraceptive versus a placebo.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Oral contraceptives

Primary outcome(s)

First in a series of collaborative studies between CVSU, Obs & Gynae and Vascular Biology (Clin Pharm).

Key secondary outcome(s))

Not provided at time of registration

Completion date

31/12/2005

Eligibility

Key inclusion criteria

Study 1 - 25 women who have developed significant BP elevation and 25 who have never suffered raised BP during pregnancy.

Study 2 - 50 women with a history of raised BP in association with taking oral contraceptive.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/08/2000

Date of final enrolment

31/12/2005

Locations

Countries of recruitment

United Kingdom

England

Study participating centre Clinical Pharmacology

London United Kingdom W2 1NY

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

St Mary's NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration