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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

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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

Primary study design
Interventional

Study design
Randomised controlled trial

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