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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/08/2000

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

Age group
Adult

Sex
Female

Target number of participants
75

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
England

United Kingdom

Study participating centre
Clinical Pharmacology
London
United Kingdom
W2 1NY

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
St Mary's NHS Trust (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