

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Neil Poulter

Contact details
Clinical Pharmacology
Cardiovascular Studies Unit
St Mary's Hospital
Praed Street
London
United Kingdom
W2 1NY
+44 20 7594 3445
n.poulter@ic.ac.uk

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 progestogen 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 progestogen-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