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Tadalafil: effects on blood pressure and arterial stiffness in systolic hypertension

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/09/2004	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 10/09/2008	**Condition category** Circulatory System	[_] Individual participant data [_] 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
N0544129338

Study information

Scientific Title

Study objectives
Does the selective phosphodiesterase-5 inhibitor tadalafil reduce arterial stiffness and blood pressure in systolic 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
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Hypertension

Interventions
The project will assess the effects of a single dose of the selective phosphodiesterase-5 inhibitor tadalafil on arterial stiffness and blood pressure in patients with systolic hypertension. Subjects will visit the Vascular Research Clinics for a screening visit and two study visits and will receive either placebo or tadalafil on each study visit. Measurements of blood pressure and arterial stiffness will be made at baseline and at hourly intervals for four hours following administration of the drug or placebo.

Intervention Type
Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)
Tadalafil

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
11/08/2003

Completion date
10/08/2006

Eligibility

Key inclusion criteria
15 subjects over 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
15

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
11/08/2003

Date of final enrolment
10/08/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Clinical Pharmacology Unit
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Department of Health

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

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Cambridge Consortium - Addenbrooke's (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