

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

Submission date 30/09/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 10/09/2008	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

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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