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Improving symptoms of intermittent claudication in patients with erectile dysfunction and peripheral vascular disease: a pilot study assessing the benefit of daily dosing with Cialis (tadalafil) 10 mg

Submission date 18/09/2007	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 05/12/2007	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 10/07/2017	**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

Protocol serial number
GJ001 PVD

Study information

Scientific Title
Improving symptoms of intermittent claudication in patients with erectile dysfunction and peripheral vascular disease: a pilot study assessing the benefit of daily dosing with Cialis (tadalafil) 10 mg

Study objectives
Daily dosing with the Phosphodiesterase type 5 (PDE 5) inhibitor tadalafil (10 mg) (for a 14-day period) may improve symptoms of claudication in patients with erectile dysfunction and peripheral vascular disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
St Thomas' Hospital Local Research Ethics Committee, 09/01/2007, ref: 06/Q0702/162

Study design
Prospective randomised double-blind placebo-controlled cross-over pilot study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Erectile dysfunction, peripheral vascular disease

Interventions
Suitably screened and consenting patients will undertake an Exercise Tolerance Test (ETT) (modified Bruce protocol). Once baseline is established (two tests, 2 weeks apart), Tadalafil 10 mg daily or placebo will be prescribed for a 14 day period. ETT will then be repeated. A weeks wash-out will be observed. A repeat ETT will be undertaken and the patient prescribed either placebo or tadalafil for a further 14 day period. ETT will be repeated. A final follow up occurs one week after this, and with a one week run in, this makes the total duration of this study 7 weeks.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome(s)

Total number of minutes/seconds on the exercise treadmill. Time to first report of leg pain will be recorded, measured at the end of weeks 3, 4 and 6

Key secondary outcome(s))
Change in score on the Walking Impairment Questionnaire and the Peripheral Artery Disease Symptom Scale, measured at the end of weeks 3, 4 and 6

Completion date
01/04/2008

Eligibility

Key inclusion criteria
1. Male aged 40 - 80 years
2. Erectile dysfunction (Sexual Health Inventory for Men [SHIM] score less than 21)
3. Peripheral vascular disease (PVD) (confirmed by previous ultrasound studies)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Key exclusion criteria
1. Contraindication to PDE 5 inhibitor
2. Inability to undertake an exercise tolerance test

Date of first enrolment
19/09/2007

Date of final enrolment
01/04/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

St Thomas' Hospital
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
Guy's and St Thomas' NHS Foundation Trust (UK)

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Charity

Funder Name
The Friend's of Guy's Hospital (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration