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Erectile dysfunction and statins: a randomised controlled trial (RCT)

Submission date	Recruitment status	[X] Prospectively registered
12/08/2008	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/09/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/06/2015	Urological and Genital Diseases	

Plain English summary of protocol
http://www.nres.npsa.nhs.uk/researchsummaries/?entryid29=20579&q=0%c2%ac08%2fH0301%2f74%c2%ac

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RHF0001

Study information

Scientific Title
Erectile dysfunction: a randomised controlled trial of lipid lowering with simvastatin (EDS trial)

Acronym
EDS trial

Study objectives
Primary hypothesis:
In men with untreated erectile dysfunction (ED) but no other cardiovascular risk factors, not currently receiving lipid lowering treatment, treatment with simvastatin improves erectile function.

Secondary hypotheses:
1. The improvement in erectile function leads to an improvement in sexual health related quality of life
2. The improvement in erectile function is related to a reduction in low-density lipoprotein (LDL) cholesterol and improvement in endothelial function
3. Treatment of ED with simvastatin is cost effective

On 05/07/2011 the overall trial end date was changed from 30/11/2009 to 30/09/2011.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Essex 1 Research Ethics Committee, 06/08/2008, ref: 08/H0301/74

Study design
Randomised double-blind placebo-controlled parallel-group multicentre 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
Erectile dysfunction caused by vascular impairment

Interventions
Simvastatin one 40 mg tablet orally daily at bedtime for 6 months or matched placebo one tablet orally daily at bedtime.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
Erectile dysfunction measured by the 5 item version of the International Index of Erectile Function (IIEF-5)
All primary and secondary outcomes will be assessed at baseline and 6 months.

Secondary outcome measures
1. Erectile function as measured by the Sexual Encounter Profile diaries
2. Quality of life (QOL), assessed by the Male Erectile Dysfunction specific questionnaire (MED-QOL) and euroqol EQ-5D
3. Total LDL, HDL cholesterol in fasting blood samples
4. Use of health services and cost of statins
5. Endothelial function measured by pulse wave analysis in a 10% sub-sample
All primary and secondary outcomes will be assessed at baseline and 6 months.

Overall study start date
01/10/2008

Completion date
30/09/2011

Eligibility

Key inclusion criteria
1. Men aged 40 years and over
2. In a stable heterosexual relationship for at least 6 months
3. No clinically overt cardiovascular risk factors other than raised cholesterol
4. Not currently on lipid or erectile dysfunction therapy
5. Untreated erectile dysfunction defined as score <22 on the International Index of Erectile Function 5 item questionnaire

Participant type(s)
Patient

Age group
Adult

Sex

Male

Target number of participants
170

Key exclusion criteria
1. Diabetes, past history of myocardial infarction, hospitalised angina or stroke
2. Hypertension - systolic blood pressure >=170 mmHg, diastolic >=100 mmHg
3. Ratio total:high-density lipoproteins (HDL) cholesterol >=6
4. Total cardiovascular risk >= 20% over next 10 years
5. Current lipid lowering therapy
6. Erectile dysfunction therapy in the last 3 months
7. Hypogonadism
8. Chronic liver disease or abnormal liver function
9. Severe renal disease or evidence of impaired renal function
10. Inflammatory muscle disease or evidence of muscle problems
11. Concomitant administration of contra-indicated drugs: itraconazole, ketoconazole, HIV protease inhibitors, erythromycin, telithromycin and nefazodone
12. Concomitant administration of other drugs associated with increased risk of myopathy /rhabdomyolysis: ciclosporin, danazol and fusidic acid
13. Galactose intolerance, Lapp lactase deficiency or glocose-galactose malabsorption

Date of first enrolment
01/10/2008

Date of final enrolment
28/07/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Hertfordshire
Hatfield
United Kingdom
AL10 9AB

Sponsor information

Organisation
University of Hertfordshire (UK)

Sponsor details
c/o Prof John Senior
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Sponsor type
University/education

Website
http://www.herts.ac.uk

ROR
https://ror.org/0267vjk41

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR), Research for Patient Benefit (RfPB) (UK) (ref: PB-PG-0107-11391)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/12/2011		Yes	No
Results article	results	01/02/2013		Yes	No
	results				

Results article	05/03/2014	Yes	No