ISRCTN71832219 https://doi.org/10.1186/ISRCTN71832219

Is it feasible, acceptable and motivating to show patients attending a lipid clinical ultrasound images of atheromatous plaque in their carotid arteries?

Submission date
12/09/2003

Recruitment status
No longer recruiting

Registration date
12/09/2003

Overall study status
Completed

Last Edited
26/06/2008

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
N0051117057

Study information

Scientific Title

Study objectives
1. That using portable ultrasound to identify carotid atheroma in patients attending a hospital lipid clinic is feasible and acceptable to patients
2. That images of carotid atheroma motivate patients to engage in behaviours to reduce the risk of cardiovascular disease

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)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Cardiovascular: Carotid atheroma

Interventions
A between subjects design in which 200 patients will be randomly allocated to one of two groups: (1) scanned (2) not scanned. Assuming that ultrasound will detect plaque in 50% of patients, this sample gives sufficient power to detect a medium effect size. Between group comparisons will be of cognitions known to precede behaviour change (ie prescriptions of severity of cardiovascular disease, risk and response efficacy (ie giving up smoking will reduce risk), understanding of the results of the scan, acceptability of the scan and fear. Prevalence of carotid atheroma and recruitment rates will be recorded.

Intervention Type

Other

Phase
Not Specified

Primary outcome measure
If successful the results in this study will be used to develop a randomised controlled trial of the impact of imaging carotid atheroma to motivate cardiovascular risk reducing behaviour change.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2002

Completion date
01/09/2003

Eligibility

Key inclusion criteria
200 patients attending a routine lipid clinic.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
200

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/09/2002

Date of final enrolment
01/09/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Brighton & Sussex University Hospitals NHS Trust (RSCH)
Brighton
United Kingdom
BN2 5BE

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
Brighton and Sussex University Hospitals 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results		01/04/2004		No	No