

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	☐ Prospectively registered ☐ Protocol
Registration date 12/09/2003	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 26/06/2008	Condition category Circulatory System	☐ 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

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

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(s)

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.

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/09/2003

Eligibility

Key inclusion criteria

200 patients attending a routine lipid clinic.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

Brighton & Sussex University Hospitals NHS Trust (RSCH)

Brighton

United Kingdom

BN2 5BE

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

Brighton and Sussex University Hospitals NHS Trust (UK)

Results and Publications

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