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

Submission date	Recruitment status	Prospectively registered
12/09/2003	No longer recruiting	[_] Protocol
Registration date	Overall study status	[] Statistical analysis plan
12/09/2003	Completed	[X] Results
Last Edited	Condition category	[] Individual participant data
26/06/2008	Circulatory System	

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

 That using portable ultrasound to identify carotid atheroma in patients attending a hospital lipid clinic is feasible and acceptable to patients
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

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type Abstract results Details Date created 01/04/2004

Date added

Peer reviewed? No Patient-facing? No