ISRCTN27140757 https://doi.org/10.1186/ISRCTN27140757

A randomised, controlled trial in primary care of a nicotine replacement therapy (NRT) assisted cessation intervention amongst adult smokers with established vascular disease to confirm effectiveness, safety and genetic influences

Submission date 19/01/2005	**Recruitment status** Stopped	[X] Prospectively registered [_] Protocol
Registration date 01/04/2005	**Overall study status** Stopped	[_] Statistical analysis plan [_] Results
Last Edited 03/03/2008	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
RESCINDING

Study objectives
Not provided at time of registration.

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 disease

Interventions
Nicotine replacement therapy in the form of patches versus placebo

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Not provided at time of registration.

Secondary outcome measures
Not provided at time of registration.

Overall study start date
01/07/2005

Completion date
30/06/2008

Reason abandoned (if study stopped)
TRIAL TERMINATED BEFORE RECRUITMENT started due to lack of funding

Eligibility

Key inclusion criteria
All smokers (self-report ≥10 cigarettes per day) aged 18 years and over who wish to stop with (at least) one of the following diagnoses:
1. Ischaemic Heart Disease:
i. Stable Angina, clinically or exercise electrocardiogram (ECG) diagnosed
ii. Myocardial infarction more than 2 months previously with recovery uncomplicated by any rhythm disturbances other than atrial fibrillation
2. Cerebrovascular disease: No exclusions
3. Peripheral vascular disease: No exclusions

Participant type(s)
Patient

Age group
Not Specified

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
2400

Key exclusion criteria
1. Patients the GP, for whatever reason, does not wish to include
2. Known skin hypersensitivity to nicotine, plasters or widespread active eczema/psoriasis or other skin conditions that would restrict patch application
3. Pregnant or breast feeding women or those who are not using reliable contraceptive methods

4. Phaeochromocytoma/Hyperthyroidism and severe renal and/or hepatic impairment
5. Severe (life threatening) arrhythmia
6. Command of English (+/- interpreter) or impairment of faculties does not allow informed consent

Date of first enrolment
01/07/2005

Date of final enrolment
30/06/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
General Practice Research Group
Oxford
United Kingdom
OX2 2BE

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
University Offices
Wellington Square
Oxford
England
United Kingdom
OX1 2JD
+44 (0)1865 270000
research.services@admin.ox.ac.uk

Sponsor type
University/education

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

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (Grant number: G0200247)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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