

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/04/2005	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 03/03/2008	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Not Specified

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(s)

Not provided at time of registration.

Key secondary outcome(s)

Not provided at time of registration.

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

Healthy volunteers allowed

No

Age group

Not Specified

Lower age limit

18 years

Sex

Not Specified

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. Pheochromocytoma/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

United Kingdom

England

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

Sponsor information

Organisation
University of Oxford (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, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration