

# 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

<b>Submission date</b> 19/01/2005	<b>Recruitment status</b> Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 01/04/2005	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 03/03/2008	<b>Condition category</b> 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

**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  $\geq 10$  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. 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**

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

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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