

A pragmatic randomised controlled trial to test the efficacy of nortriptyline plus nicotine replacement therapy (NRT) versus a placebo plus NRT in helping smokers to stop and testing the role of noradrenergic and dopaminergic genetic variants in smoking cessation

Submission date 05/07/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 25/07/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 21/12/2011	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
<http://www.scanag.bham.ac.uk>

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

MREC/03/7/053

Study information

Scientific Title

Acronym

SCANAG - Smoking Cessation and Nortriptyline and Genetics

Study objectives

1. To show whether nortriptyline plus NRT is more effective than NRT alone in smoking cessation
2. To explore whether allelic variants coding for components of the noradrenergic pathways interact with pharmacological treatment and are related to withdrawal severity and successful quitting
3. To test a previous exploratory finding that allelic variants coding for components of the dopaminergic pathways interact with NRT to predict quitting success

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee (ref: MREC/03/7/053).

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Smoking cessation

Interventions

NRT plus nortriptyline/placebo.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Nortriptyline and nicotine replacement therapy (NRT)

Primary outcome measure

Six months of continuous abstinence biochemically confirmed.

Secondary outcome measures

1. Seven-day point prevalence
2. Twelve-month continuous abstinence

Overall study start date

01/08/2003

Completion date

31/07/2005

Eligibility**Key inclusion criteria**

1. Smoked at least 10 cigarettes per day on average over the past year.
2. Want to quit
3. Prepared to use NRT and the trial drug
4. Using an NHS stop smoking service

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

900

Key exclusion criteria

1. Pregnant or breast feeding or planning to do so in the next 3 months
2. Not clinically suitable to use NRT according to data sheet
3. Not clinically suitable to use nortriptyline according to data sheet

Date of first enrolment

01/08/2003

Date of final enrolment

31/07/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Department of Primary Care & General Practice

Birmingham

United Kingdom

B15 2TT

Sponsor information

Organisation

University of Birmingham (UK)

Sponsor details

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Sponsor type

University/education

Website

<http://www.scanag.bham.ac.uk>

ROR

<https://ror.org/03angcq70>

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK (CRUK) (UK) (ref: C9278/A3461)

Alternative Name(s)

CR_UK, Cancer Research UK - London, CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	31/05/2008		Yes	No