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	Prospectively registered
		☐ Protocol
Registration date	Overall study status	Statistical analysis plan
25/07/2005	Completed	[X] Results
Last Edited	Condition category	☐ Individual participant data
21/12/2011	Mental and Behavioural Disorders	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number 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

Study type(s)

Treatment

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(s)

Six months of continuous abstinence biochemically confirmed.

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre Department of Primary Care & General Practice Birmingham

Sponsor information

Organisation

University of Birmingham (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, Cancer Research UK (CRUK), CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Results article Results 31/05/2008 Yes No

Study website Study website 11/11/2025 No Yes