ISRCTN57852484 https://doi.org/10.1186/ISRCTN57852484

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

Registration date
25/07/2005

Overall study status
Completed

Last Edited
21/12/2011

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

Contact name
Dr Paul Aveyard

Contact details
Department of Primary Care & General Practice
University of Birmingham
Birmingham
United Kingdom
B15 2TT
+44 (0)121 414 8529
p.n.aveyard@bham.ac.uk

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
Dr Brendan Laverty
Research & Enterprise Services
University of Birmingham
Birmingham
England
United Kingdom
B15 2TT
+44 (0)121 414 8529
p.n.aveyard@bham.ac.uk

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