

Using genotype to tailor prescribing of Nicotine Replacement Therapy (NRT): a randomised controlled trial assessing impact upon medication adherence

Submission date 20/03/2006	Recruitment status No longer recruiting	☒ Prospectively registered
Registration date 17/05/2006	Overall study status Completed	☒ Protocol
Last Edited 14/02/2018	Condition category Mental and Behavioural Disorders	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)

2006-000106-24

Protocol serial number

G0500274 (MRC ref no)

Study information

Scientific Title

Using genotype to tailor prescribing of Nicotine Replacement Therapy (NRT): a randomised controlled trial assessing impact upon medication adherence

Study objectives

Adherence to NRT is greater when given feedback that NRT is tailored to genotype as opposed to heaviness of smoking.

The trial is 1 of 3 studies that make up an MRC-funded programme of research: GRAB (Genetic Risk And Behaviour change)

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added as of 03/08/2007:

Hertfordshire 1 Research Ethics Committee, approved in June 2006 (ref: 06/Q0201/21; Protocol No.1)

Primary study design

Interventional

Study design

Open-label, parallel group, randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Smoking

Interventions

Participants will be divided into two groups of equal size by randomisation. One group will be informed that prescribing for NRT is based upon DNA information and addiction, and the other group informed that it is based on addiction alone.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Nicotine replacement therapy

Primary outcome(s)

The proportion of all NRT consumed in the first 4 weeks of quitting or to the point of relapse, whichever is the sooner. This will be measured by self-report daily diary, backed up by 'pill count reconciliation' with the diary at the clinic. If pill counts are discrepant with the diary, this will be discussed and reconciled at the clinic visit.

Key secondary outcome(s)

1. Responses to the Mood and Physical Symptoms Scale, a measure of nicotine withdrawal symptoms
2. Point prevalence of 14-day complete abstinence measured at 28 days after smoking cessation
3. Response efficacy of NRT
4. State anxiety

Completion date

21/05/2009

Eligibility**Key inclusion criteria**

Eligible participants are:

1. Motivated quitters attending the participating NHS smoking cessation clinics
2. Participants must be smokers smoking 10 or more cigarettes per day over the last 12 months
3. Aged 18 and over
4. Living in the British Isles

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Non-smokers
2. Smokers smoking less than 10 cigarettes daily over the last 12 months
3. Aged under 18
4. Living outside the British Isles
5. Cigar/pipe smokers
6. NRT contraindications (e.g. pregnant or lactating women)
7. Those with previous severe adverse reactions to NRT
8. Currently taking medication for smoking cessation that they are unwilling to cease taking or medication with a known influence on smoking cessation that they cannot stop

Date of first enrolment

21/05/2006

Date of final enrolment

21/05/2009

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

King's College London

London

United Kingdom

SE1 6SP

Sponsor information

Organisation

King's College London (UK)

ROR

<https://ror.org/0220mzb33>

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (UK) (ref: G0500274)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2012		Yes	No
Results article	results	01/09/2013		Yes	No
Results article	results	29/01/2018		Yes	No
Protocol article	protocol	09/11/2010		Yes	No