General practice study of Nicotine Replacement Therapy (NRT) assisted smoking cessation

Submission date 12/10/2005	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 16/11/2005	Overall study status Completed	 Statistical analysis plan [X] Results
Last Edited 20/12/2011	Condition category Mental and Behavioural Disorders	Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N0032117035

Study information

Scientific Title

Acronym Patch In Practice (PIP)

Study objectives

 Assess whether extremes of behavioural support make a difference to quit rates
 Study whether an individual's response to NRT is influenced by genetic constitution
 Describe the relationship between nicotine load whilst smoking and that derived from transdermal patch

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) Treatment

Participant information sheet

Health condition(s) or problem(s) studied Smoking cessation

Interventions

PIP is an open randomised controlled trial of two levels of behavioural support. One of the aims of the study is to assess response of moderately addicted smokers making a Nicotine Replacement Therapy (NRT) assisted quit attempt when randomised to low or moderate behavioural support within general practice.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Nicotine

Primary outcome measure

Continuous abstinence by self-report and carbon dioxide at 1 week, 4 weeks, and 12 weeks in relation to genotype and 4 weeks for replacement.

Secondary outcome measures

Continuous abstinence at 1, 3, 6 and 12 months
 Point prevalence abstinence at 1 week, 4 weeks, 3, 6 and 12 months by self report

Overall study start date

01/08/2002

Completion date

31/03/2006

Eligibility

Key inclusion criteria

1. Greater than 18 years of age

2. Smoke 10 or more cigarettes per day

3. Wish to try to give up completely

Participant type(s)

Patient

Age group Adult

Lower age limit 18 Years

Sex

Both

Target number of participants 1000

Key exclusion criteria 1. Pregnant or breast feeding 2. Using NRT or Zyban

Date of first enrolment 01/08/2002

Date of final enrolment 31/03/2006

Locations

Countries of recruitment England

United Kingdom

Study participating centre Smoking Research Group Oxford United Kingdom OX2 6HE

Sponsor information

Organisation University of Oxford (UK)

Sponsor details University Offices Wellington Square Oxford England United Kingdom OX1 2JD

Sponsor type University/education

Website http://www.ox.ac.uk/

ROR https://ror.org/052gg0110

Funder(s)

Funder type Charity

Funder Name

Cancer Research UK (CRUK) (UK)

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	01/10/2007		Yes	No