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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Michael Murphy

Contact details
Smoking Research Group
Department of clinical Pharmacology
University of Oxford
Radcliffe Infirmary
Woodstock Road
Oxford
United Kingdom
OX2 6HE

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
1. Assess whether extremes of behavioural support make a difference to quit rates
2. Study whether an individual's response to NRT is influenced by genetic constitution
3. 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
1. Continuous abstinence at 1, 3, 6 and 12 months
2. 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