

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
		☒ 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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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Study participating centre

Smoking Research Group

Oxford

United Kingdom

OX2 6HE

Sponsor information

Organisation

University of Oxford (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, 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	01/10/2007		Yes	No