Nicotine nasal spray for smoking cessation in primary care

Submission date	Recruitment status	Prospectively registered		
12/03/2010	No longer recruiting	☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
15/04/2010	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
08/08/2011	Mental and Behavioural Disorders			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mr John Stapleton

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

9820384; G7804283

Study information

Scientific Title

Randomised placebo controlled trial of nicotine nasal spray for smoking cessation in primary care

Acronym

GPNNS

Study objectives

To compare the effectiveness of nicotine nasal spray and placebo when given with brief GP and nurse support in primary care.

Ethics approval required

Old ethics approval format

Ethics approval(s)

King's Lynn Medical Research Ethics Committee approved on the 21st November 1995 (ref: 95-NNNS-014 (34/95))

Study design

Multicentre randomised placebo controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Tobacco dependence

Interventions

Active or placebo nicotine nasal spray for 12 weeks plus brief primary care counseling support. Total duration of follow-up is 12 weeks.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Co-verified complete abstinence from smoking for weeks 3 to 12.

Secondary outcome measures

- 1. Co-verified complete abstinence from smoking during 12 weeks
- 2. Adverse events

Overall study start date

01/02/1996

Completion date

01/02/1999

Eligibility

Key inclusion criteria

- 1. Smokers: smoking for at least 3 years
- 2. Aged 20 60 years, either sex
- 3. Smokes 15 or more cigarettes a day
- 4. Motivated to stop

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

1200

Key exclusion criteria

- 1. Myocardial infarction within 3 years
- 2. Chronic nasal disorder
- 3. Pregnancy, intending pregnancy
- 4. Breast feeding
- 5. Current psychiatric care
- 6. Current use of psychotropic drugs

Date of first enrolment

01/02/1996

Date of final enrolment

01/02/1999

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Institute Of Psychiatry

London United Kingdom SE5 8AF

Sponsor information

Organisation

McNeil AB (Sweden) - formally Pharmacia and Upjohn

Sponsor details

Box 941 Helsingborg Sweden 251 09 GGustavs@its.jnj.com

Sponsor type

Industry

Website

http://www.mcneilab.se/contact

ROR

https://ror.org/020jwmq86

Funder(s)

Funder type

Research council

Funder Name

Kings College London (UK) - Institute of Psychiatry, staff supported by MRC Programme Grant (ref: G7804283)

Funder Name

McNeil AB (Sweden) - formally Pharmacia and Upjohn, supported trial costs

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	01/04/2011		Yes	No