

# Nicotine nasal spray for smoking cessation in primary care

|  |   |  |
|--|---|--|
| <b>Submission date</b><br>12/03/2010   | <b>Recruitment status</b><br>No longer recruiting             | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>15/04/2010 | <b>Overall study status</b><br>Completed                      | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>08/08/2011       | <b>Condition category</b><br>Mental and Behavioural Disorders | <input type="checkbox"/> Statistical analysis plan   |
|  |   | <input checked="" type="checkbox"/> Results          |
|  |   | <input type="checkbox"/> Individual participant data |

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Mr John Stapleton

**Contact details**  
Institute Of Psychiatry  
Kings College London  
Postal Box P075  
4 Windsor Walk  
London  
United Kingdom  
SE5 8AF  
j.stapleton@iop.kcl.ac.uk

## Additional identifiers

**Protocol serial number**  
9820384; G7804283

## Study information

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

**Acronym**

GPNNNS

**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

**Study type(s)**

Treatment

**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(s)**

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

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**

Institute Of Psychiatry

London

United Kingdom

SE5 8AF

**Sponsor information**

## Organisation

McNeil AB (Sweden) - formally Pharmacia and Upjohn

## 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

### 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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/04/2011   |            | Yes            | No              |