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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

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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
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))

Primary study design
Interventional

Study design
Multicentre randomised placebo controlled trial

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?
Results article	results	01/04/2011		Yes	No