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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

Contact name
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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