

Pre-treatment of nicotine for one month before quitting smoking: a randomised trial

Submission date 10/06/2005	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 25/08/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 28/07/2009	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
3200-067835

Study information

Scientific Title

Nicotine gum treatment before smoking cessation, a randomised trial

Acronym

Etude nicotine

Study objectives

Nicotine replacement therapy (NRT) taken for one month before and two months after smoking cessation will be more effective than usual care i.e. NRT for two months after the quit date.

Please note that as of 09/02/09 this record was updated to include an amended anticipated end date. The initial anticipated end date was 30/06/2011.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added 09/02/2009:

1. The Ethics Board of the Association des médecins du canton de Genève (AMG) gave approval on the 15th January 2004
2. The Ethics Board of the Faculty of Biology and Medicine, University of Lausanne gave approval on the 20th April 2006

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Informed consent document can be found at http://www.stop-tabac.ch/fr_hon/Informed_consent_pre-cessationNRT.pdf

Health condition(s) or problem(s) studied

Cigarette smoking

Interventions

Nicotine gum (4 mg) for one month before and two months after quitting smoking. The control group will receive similar gums, but only after they quit smoking, for 2 months. No placebos will be used.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Nicotine replacement therapy (NRT)

Primary outcome measure

1. Smoking status at the target quit date, and 2, 12 and 60 months thereafter. We will use the criterion recommended by the U.S. Food and Drugs Administration (FDA) to assess outcome in smoking cessation studies: not having smoked even one puff of tobacco during the previous 4 weeks, and the criterion recommended in a recent guideline: not having smoked even one puff of tobacco in the previous 7 days. At 12 months only, smoking abstinence will be verified by saliva cotinine and, if positive, by expired carbon monoxide.
2. Tobacco withdrawal symptoms at the target quit date and 2 months thereafter
3. Utilisation of nicotine gums at the target quit date and 2 months thereafter (number of gums per day and duration of use)

Secondary outcome measures

At 12 months, we will use as secondary outcome the recently recommended criterion of 6 months of continuous abstinence.

Other outcomes:

1. Quit attempts (number and duration)
2. Motivation to quit smoking
3. Confidence in ability to quit smoking, self-efficacy
4. Cigarette consumption
5. Level of dependence on cigarettes, assessed with the CDS-12 test
6. Side-effects of NRT
7. Attitudes towards NRT, in particular perception that NRT is dangerous

Overall study start date

01/09/2005

Completion date

31/12/2009

Eligibility

Key inclusion criteria

1. Smokes 15+ cigarettes per day
2. Lives in the Swiss cantons of Geneva or Vaud
3. Daily smoker for at least 3 years
4. Aged 18 years or more, either sex

5. Seriously intends to quit smoking in the next two months
6. Willing to use 4 mg nicotine gums for one month before and two months after smoking cessation
7. Willing to postpone smoking cessation until one month after enrolment in the study
8. Commits to take part in all follow-up procedures, including if he/she is attributed to the control group
9. Declares to understand and accept the control-group procedure
10. Signs the informed consent form
11. Has access to internet at home or at work and provides a valid e-mail address
12. Provides a telephone number
13. Provides a health status questionnaire signed by a physician and by the participant

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

860 (amended as of 09/02/2009 = 314 participants)

Key exclusion criteria

1. Current use of NRT or bupropion
2. Pregnancy, lactation or planned pregnancy
3. Unstable angina pectoris
4. Myocardial infarction or cerebral vascular accident within the last 3 months
5. Under psychiatric care or medication that might interfere with the trial
6. Alcohol or other drug problem that might interfere with the trial
7. Having a mouth pathology, and/or dental problem that might interfere with gum use

Date of first enrolment

01/09/2005

Date of final enrolment

31/12/2009

Locations**Countries of recruitment**

Switzerland

Study participating centre

IMSP CMU
Geneva 4
Switzerland
CH-1211

Sponsor information

Organisation

University of Geneva - Institute of Social and Preventive Medicine (Switzerland)

Sponsor details

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Sponsor type

University/education

Website

<http://www.unige.ch>

ROR

<https://ror.org/01swzsf04>

Funder(s)

Funder type

Industry

Funder Name

Swiss National Science Foundation (Switzerland) (ref: 3200-067835)

Alternative Name(s)

Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, SNF, SNSF, FNS

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Switzerland

Funder Name

Pfizer (Sweden) - provided nicotine gums at no charge (ref: NRA6430008)

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	08/06/2009		Yes	No