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

Submission date	Recruitment status	[X] Prospectively registered
10/06/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
25/08/2005	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/07/2009	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
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

Study type(s)
Treatment

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)
Nircotine replacement therapy (NRT)

Primary outcome(s)
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)

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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)

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, The Swiss National Science Foundation (SNSF), 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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	08/06/2009		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes