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The effect of Tabex (Cytisine) on success of attempts to stop smoking

Submission date	Recruitment status	[X] Prospectively registered
08/06/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
11/09/2006	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/10/2011	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
G0501300

Study information

Scientific Title

Acronym

TAbex Smoking Cessation (TASC) trial

Study objectives
The study aims to determine the efficacy of a standard course of Tabex (cytisine) in aiding attempts to stop smoking.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval obtained in the UK: University College London Ethics Committee, approved on 13/12 /2006 (ref: 0498/003).

Approvals obtained in Poland:
1. Ethics Committee at the Cancer Centre and Institute of Oncology, approved on 09/01/2007, Ref: 02/2007
2. Central Register of Clinical Trials (CEBK), approved on 19/03/2007, Ref: 110/UR/CEBK/03/07

Study design
Double blind placebo-controlled randomised trial with two arms

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Smoking cessation

Interventions
Smokers wanting to stop will be individually randomised to receive a course of Tabex (cytisine) for 25 days or a matched placebo. The dosage will be as currently licensed in Poland:
1. One tablet (1.5mg) every two hours (six per day) for three days
2. One tablet every 2.5 hours (five per day) from days four to 12
3. One tablet every three hours (four per day) from days 13 to 16
4. One tablet every four hours (three per day) from days 17-20
5. One tablet every six hours (two tablets daily) from days 21 to 25.
The total regimen involves 100 tablets. Smokers are instructed to stop smoking completely by the fifth day which is designated as the quit date.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Tabex (Cytisine)

Primary outcome(s)

The primary outcome measure will be self-report of abstinence from smoking or use of any tobacco products from two weeks after the quit date for twelve months with no more than five cigarettes in total during that time, confirmed by an expired air Carbon Monoxide (CO) reading at the twelve month follow-up of less than 10 ppm. Inclusion will be by intent to treat and all subjects whose smoking status cannot be determined but who are not known to have moved to an untraceable address or died will be counted as smokers.

Key secondary outcome(s))
Current secondary outcome measures as of 30/11/2010:
1. Continuous abstinence from two weeks after the quit date with no more than five cigarettes smoked in total up to six months, together with a CO of less than 10 ppm at the 6 month follow-up
2. Self-reported continuous abstinence with no cigarettes smoked during the first four weeks of treatment, supported by CO verification at the end-of-treatment session.
3. The severity of withdrawal symptoms measured using the Mood and Physical Symptoms Scale, one week after the designated quit date in smokers who have been abstinent since the quit date
4. Minor and serious adverse events reported throughout the trial
5. Depression, mood and physical symptoms reported throughout the trial.

Previous secondary outcome measures:
1. Self-reported continuous abstinence with no cigarettes smoked for weeks three and four supported by CO verification at week four
2. Continuous abstinence with no more than five cigarettes smoked in total up to 12-months, together with a CO of less than 10 ppm at the 12-month follow-up
3. The severity of withdrawal symptoms measured using the Mood and Physical Symptoms Scale, one week after the designated quit date in smokers who have been abstinent since the quit date

Completion date
31/03/2009

Eligibility

Key inclusion criteria
1. Smokers of ten or more cigarettes per day willing to attempt to stop smoking permanently
2. Willing to attend all the sessions
3. Able to read and write Polish and provide informed consent
4. Able to be contacted by telephone
5. Participants must agree not to use any other smoking cessation medications or tobacco products during the study, at least until the point where they have relapsed and will be regarded as a treatment failure.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex

All

Key exclusion criteria
1. Participants must not be undergoing treatment for any psychological disorder or medical conditions that contraindicate cytisine as listed on the data sheet (including diagnosed arterial hypertension or acute cardiovascular disease)
2. Not pregnant or breastfeeding
3. Not planning on becoming pregnant

Date of first enrolment
01/02/2007

Date of final enrolment
31/03/2009

Locations

Countries of recruitment
United Kingdom

England

Poland

Study participating centre
Department of Epidemiology and Public Health
London
United Kingdom
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Sponsor information

Organisation
University College London (UK)

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
National Prevention Research Initiative (NPRI) (UK)

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	29/09/2011		Yes	No