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Topiramate for tobacco dependence

Submission date	Recruitment status	[X] Prospectively registered
30/01/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/02/2008	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
31/05/2019	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

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
PI061462

Study information

Scientific Title
Effectiveness of topiramate for tobacco dependence in patients with depression: a randomised, controlled trial

Acronym
N/A

Study objectives
Topiramate is at least as effective like nicotine substitution therapy (NST - the standard treatment) for tobacco dependence.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Ethical Review Board of the Regional Health Authority of Aragon (Spain) in February 2007 (ref: FIS PI06/1462).

Study design
This is a controlled trial with a random allocation of patients into control group (NST) or intervention group (topiramate)

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

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, major depressive disorder

Interventions
A multi-component programme for tobacco cessation will be offered to all patients in the study. This is made up of pharmacological therapy and group cognitive-behavioural therapy. The group is made up of 7 - 12 patients with depression and tobacco dependence, and is led by two therapists (a psychologist and a family doctor) trained in group therapy and tobacco cessation. Each session lasts 90 minutes, and the structure of every session and the contents are manualised and based on the standard programmes of this type.

Pharmacological therapy consists of:
1. Control group: Nicotine Substitution Therapy (nicotine patches) at doses of 21 mg/day first and second fortnight, 14 mg/day third fortnight and 7 mg/day fourth and last fortnight
2. Intervention group: Topiramate (oral) 100 - 200 mg/day, during 2 months

The follow-up of the treatments and adverse effects will be made at the appointmets described (during the first two months of the intervention).

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Topiramate, nicotine

Primary outcome measure
The major outcome is tobacco cessation in patients with depression. The diagnosis of tobacco dependence will be made with the Spanish version of the Mini-International Neuropsychiatric Interview (MINI), substance dependence module adapted to tobacco (measured at baseline and at the end of study [month 12]). Tobacco abstinence will also be diagnosed by:
1. Self-declared abstinence
2. Self-administered Minnesota tobacco abstinence symptoms, measured at baseline, D (cessation day) -1, weeks 1, 2, 3, 4, 8, 12, and months 4, 5, 6, 8, 10 and 12
3. Expired air carbon monoxide, measured at baseline, D (cessation day) -1, weeks 1, 2, 3, 4, 8, 12, and months 4, 5, 6, 8, 10 and 12
4. Cotinine in saliva, measured at baseline, D (cessation day) -1, weeks 1, 2, 3, 4, 8, 12, and months 4, 5, 6, 8, 10 and 12

Secondary outcome measures
The diagnosis of depressive disorder will be made with the Spanish version of the MINI psychiatric interview, depression module, and the severity of the depression with the Spanish version of the Zung Self-Rating Depression Scale (measured at baseline and at the end of study [month 12]). In addition, the following will be also recorded:
1. Tobacco dependence as measured by the Spanish version of the Fagerström test for Nicotine Dependence, measured at baseline, D (cessation day) -1, weeks 1, 2, 3, 4, 8, 12, and months 4, 5, 6, 8, 10 and 12
2. Anxiety trait and state as measured by the Spanish version of the State-Trait Anxiety Inventory (STAI), measured at baseline, D (cessation day) -1, weeks 1, 2, 3, 4, 8, 12, and months 4, 5, 6, 8, 10 and 12
3. Impulsivity as measured by the Spanish version of the Plutchik scale of impulsivity, measured at baseline, D (cessation day) -1, weeks 1, 2, 3, 4, 8, 12, and months 4, 5, 6, 8, 10 and 12
4. Visual analogue scale for efficacy self-perception, measured at baseline, D (cessation day) -1, weeks 1, 2, 3, 4, 8, 12, and months 4, 5, 6, 8, 10 and 12
5. Pharmacological side-effects

Overall study start date
01/04/2008

Completion date

31/12/2009

Eligibility

Key inclusion criteria
1. Patients aged 18 - 65 years, either sex
2. Able to understand and read Spanish
3. Fulfill criteria for major depression (Diagnostic and Statistical Manual of Mental Disorders, 4th edition [DSM-IV] criteria)
4. Scores on the Zung Self-Rating Depression Scale less than 60 (implying minimal to mild depression)
5. Smoke more than 20 cigarettes/day
6. Fulfil preparation state of change according to Prochaska and DiClemente classification
7. Voluntarily ask for a tobacco cessation therapy
8. Sign informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150 patients (75 patients in each branch of treatment)

Total final enrolment
180

Key exclusion criteria
1. Active psychosis and/or treatment with antipsychotic drugs
2. Alcohol or drug abuse
3. Pregnancy or lactation

Date of first enrolment
01/04/2008

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
Spain

Study participating centre
Avda. Gomez Laguna 52, 4 D
Zaragoza
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Sponsor information

Organisation
The Carlos III Health Institute (Instituto de Salud Carlos III) (Spain)

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Sponsor type
Research organisation

Website
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ROR
https://ror.org/00ca2c886

Funder(s)

Funder type
Government

Funder Name
Carlos III Health Institute of the Spanish Ministry of Health and Consumption (Fondo de Investigaciones Sanitarias - Instituto de Salud Carlos III-Ministerio de Sanidad y Consumo) (Spain) (ref: PI06/1462)

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	07/05/2008	31/05/2019	Yes	No