

Topiramate for tobacco dependence

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| Submission date 30/01/2008 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered |
| Registration date 27/02/2008 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 31/05/2019 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <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

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)

Treatment

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 appointments 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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

Spain

50009

Sponsor information**Organisation**

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

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

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 |