

# Topiramate for tobacco dependence

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

### Contact name

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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 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 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  
Spain  
50009

## Sponsor information

### Organisation

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

### Sponsor details

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### Sponsor type

Research organisation

### Website

<http://www.isciii.es>

### 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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 07/05/2008   | 31/05/2019 | Yes            | No              |