

Baclofen for maintenance treatment of opioid dependence: A randomised double-blind placebo-controlled clinical trial

Submission date

14/11/2003

Recruitment status

No longer recruiting

Registration date

17/11/2003

Overall study status

Completed

Last Edited

01/10/2007

Condition category

Mental and Behavioural Disorders

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ Results

☐ 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

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

G36

Study information

Scientific Title

Study objectives

Not provided at time of registration

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Opioid dependence

Interventions

A total of 40 opioid-dependent patients were detoxified and randomly assigned to receive baclofen (20 mg three times a day [t.i.d.]) or placebo (in identical-appearing tablets t.i.d.) in a 12-week, double blind, parallel-group trial.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Baclofen

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/11/2001

Completion date

01/11/2002

Eligibility

Key inclusion criteria

Subjects were eligible for the study if they:

1. Met DSM-IV criteria for opioid dependence
2. Were detoxified at our addiction clinic
3. Were between 18 and 60 years of age
4. Gave written informed consent for participation in the study

Opioid dependence (according to Diagnostic and Statistical Manual of Mental Disorders, fourth edition [DSM-IV] criteria).

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

40

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/11/2001

Date of final enrolment

01/11/2002

Locations

Countries of recruitment

Iran

Study participating centre
Roozbeh Psychiatric Hospital
Tehran
Iran
13337

Sponsor information

Organisation

Roozbeh Addiction Department (Iran)

Sponsor details

Roozbeh Psychiatric Hospital
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Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/019mzt973>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Roozbeh Addiction Department (Iran) (ref: G36)

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	18/11/2003		Yes	No