

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	<input type="checkbox"/> Prospectively registered
Registration date 17/11/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 01/10/2007	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

Contact name

Dr Seyed Mohammad Assadi

Contact details

Roozbeh Psychiatric Hospital

South Kargar Avenue

Tehran

Iran

13337

+98 (0)21 542222

assadism@sina.tums.ac.ir

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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)

ROR

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

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Roozbeh Addiction Department (Iran) (ref: G36)

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	18/11/2003		Yes	No