# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

11 Jul 2026

## Investigating the effectiveness of adding Clonidine and Gabapentin to Buprenorphine during detoxification of children and adolescents with Opioid Use Disorders

### Protocol summary

**Study aim**
Investigating the effectiveness of adding Clonidine and Gabapentin to Buprenorphine during detoxification of children and adolescents with Opioid Use Disorders

**Design**
Clinical trial with control group with randomized parallel groups on 40 patients

**Settings and conduct**
40 children aged 5 to 18 years with opioid use disorder will be studied according to the process of block randomization in two groups (buprenorphine) and (buprenorphine and clonidine and gabapentin). To collect information, the Opioid Withdrawal Clinical Symptoms Scale and the Opioid Withdrawal Mental Symptoms Scale will be completed on days 1 to 14. In both groups, buprenorphine will start at a dose of 2 mg per day and a maximum of 8 mg per day. Patients in the intervention group will also receive clonidine at a starting dose of 0.1 mg and then increase to 0.2 mg and gabapentin 100 to 300 mg three times daily.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria:Diagnosis of opioid use disorder based on DSM-5 By child and adolescent psychiatrist ;age 5-18 years old. Exclusion Criteria:allergy to buprenorphine or clonidine or gabapentin; chronic or inflammatory diseases ; serious psychiatric illnesses ; Dissatisfaction of the patient's parent or Legal guardian to continue the plan

**Intervention groups**
The control group receive 2 to 8 mg buprenorphine according to the protocol and in the intervention group receive 0.1 mg of clonidine in divided doses in first day then increased to 0.2 mg in latter days and gabapentin capsules at a dose of 100 to 300 mg every 8 hours from the first day in addition to buprenorphine.

**Main outcome variables**
Withdrawal symptoms according to psychiatrist examination and patient report

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20110411006168N4**
Registration date: **2021-08-29, 1400/06/07**
Registration timing: **prospective**

Last update: **2021-08-29, 1400/06/07**
Update count: **0**

**Registration date**
2021-08-29, 1400/06/07

**Registrant information**

**Name**
Mahin Eslami Shahrbabki

**Name of organization / entity**
Kerman University of Medical Sciences

**Country**
Iran (Islamic Republic of)

**Phone**
+98 34 1211 6328

**Email address**
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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2021-09-06, 1400/06/15

**Expected recruitment end date**
2021-10-22, 1400/07/30

**Actual recruitment start date**
empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigating the effectiveness of adding Clonidine and Gabapentin to Buprenorphine during detoxification of children and adolescents with Opioid Use Disorders

**Public title**

Investigating the effectiveness of adding Clonidine and Gabapentin to Buprenorphine during detoxification of children and adolescents with Opioid Use Disorders

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Diagnosis of opioid use disorder based on DSM-5 by a child and adolescent psychiatrist age 5-18 years old

**Exclusion criteria:**

Allergy to buprenorphine or clonidine or gabapentin. Chronic or inflammatory diseases (heart, lung, liver, kidney or neurological diseases such as epilepsy). Serious psychiatric illnesses such as schizophrenia and other psychotic disorders, acute phase of bipolar disorder and moderate to severe mental disability. Dissatisfaction of the patient's parent or Legal guardian to continue the plan.

**Age**

From **5 years** old to **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

This clinical study will be conducted using blocked randomization scheme. In this trial with 40 individuals, this scheme randomizes individuals by performing a block randomization with equal block sizes of four participant randomly ordered, making sure two of them are with the “A” card representing treatment group and two with the “B” card representing control group. Allocation proceeds by sortition selecting one of the ordering of each block to finalize a sequence of 40 aforementioned cards. Each card is placed in an envelope, sealed and placed in the same order. Finally, for each patient enters the study, the corresponding envelope to their sequence is opened to determine the group allocation.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**

**Name of ethics committee**

Working Group / Research Ethics Committee of Kerman University of Medical Sciences

**Street address**

Kerman, the beginning of Haft Bagh Alavi axis, campus of University of Medical Sciences

**City**

Kerman

**Province**

Kerman

**Postal code**

7616913555

**Approval date**

2021-05-03, 1400/02/13

**Ethics committee reference number**

IR.KMU.REC.1400.074

## Health conditions studied

**1**

**Description of health condition studied**

Opioid Use Disorders

**ICD-10 code**

F11.1

**ICD-10 code description**

Opioid abuse

## Primary outcomes

**1**

**Description**

Withdrawal symptoms according to psychiatrist examination and patient report

**Timepoint**

days 1 to 14

**Method of measurement**

Clinical opioid withdrawal scale and subjective opioid withdrawal scale

## Secondary outcomes

**1**

**Description**

Drug side effects

**Timepoint**

day 1 to 14

**Method of measurement**

Checklist of drug side effects

## Intervention groups

### 1

**Description**
Control group: after emergence of withdrawal symptoms, an average of 2 mg of buprenorphine is started in two divided doses and if needed, 2 mg of buprenorphine up to a maximum of 8 mg is given to patients every 2 hours, and the second day is equivalent to the first day dose or if mild to moderate withdrawal symptoms are emerged, 2-4 mg buprenorphine more than the first day (maximum 8 mg) will be prescribed.From the 4th day, gradually decrease to 0.5 to 1 mg daily to be discontinued

**Category**
Treatment - Drugs

### 2

**Description**
Intervention group: After emergence of withdrawal symptoms, an average of 2 mg of buprenorphine is started in two divided doses and if needed, 2 mg of buprenorphine up to a maximum of 8 mg is given to patients every 2 hours, and the second day is equivalent to the first day dose or if mild to moderate withdrawal symptoms are emerged, 2-4 mg buprenorphine more than the first day (maximum 8 mg) will be prescribed. From the 4th day, gradually decrease to 0.5 to 1 mg daily to be discontinued. In addition on the first day, 0.1 mg of clonidine is given to patients in divided doses two to three times a day, and on the second day, the dose of clonidine is increased to 0.2 mg, and the Gabapentin capsule with a dose of 100 to 300 mg every 8 hours is prescribed with clonidine starting from day one.

**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Shahid Beheshti Hospital ,Jomhori Blvd, Kerman,IRAN

**Full name of responsible person**
Dr Mahin Eslami Shahrbabki

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
Kerman University of Medical Sciences

**Full name of responsible person**
Dr.Vahid Sheibani

**Street address**
Opposit of Besaat Clinic ,Ebn -e-sina street, Jahad Blv,Kerman

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**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**
Yes

**Title of funding source**
Kerman University of Medical Sciences

**Proportion provided by this source**
100

**Public or private sector**
Public

**Domestic or foreign origin**
Domestic

**Category of foreign source of funding**
*empty*

**Country of origin**

**Type of organization providing the funding**
Academic

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**
Kerman University of Medical Sciences

**Full name of responsible person**
Dr. Mahin Eslami Sharbabaki

**Position**
MD,assistant professor

**Latest degree**
Subspecialist

**Other areas of specialty/work**
Psychiatrics

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available
**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available
**Statistical Analysis Plan**
Undecided - It is not yet known if there will be a plan to make this available
**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available
**Clinical Study Report**
Undecided - It is not yet known if there will be a plan to make this available
**Analytic Code**
Undecided - It is not yet known if there will be a plan to make this available
**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available
**Title and more details about the data/document**
At the end of the study and after its approval and analysis, the study is supposed to be in the form of an article, in which part of the data is mentioned and not necessarily all of it. The data will be available after the patients are not identified, and specialized and enthusiastic people will be able to access the participants' data file.
**When the data will become available and for how long**
After completing the study and obtaining permission from the project manager and the University of Medical Sciences. Approximately 1 to 2 years after the end of the study.
**To whom data/document is available**
Prior to the publication of the data, only the project executor and the main project partners.
**Under which criteria data/document could be used**
Files are provided to specific individuals only after the completion of the study and with the permission of the University of Medical Sciences for the use of data for use in meta-analysis studies and systematic reviews.
**From where data/document is obtainable**
executor of plan. Main contributors. Kerman University of Medical Sciences and Neuroscience Center
**What processes are involved for a request to access data/document**
In order to receive the published files, the necessary permits must be obtained from Kerman University of Medical Sciences and the Center for Neuroscience and Executors.
**Comments**