Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

The efficacy of Buspirone on withdrawal symptoms in children and adolescents with substance use disorder on treatment with buprenorphine

Protocol summary

Study aim
Investigating the effectiveness of adding buspirone 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
Forty children aging 5-18 with opioid use disorder will be studied after block randomization into two groups (buprenorphine only; buprenorphine and buspirone). For data collection, the "Opioid withdrawal clinical symptom scale" and "Opioid withdrawal mental symptom scale" will be filled from days 1 to 14. In both groups buprenorphine will be administered at a dose of 2mg to a maximum of 8mg per day. The intervention group will receive buspirone at a dose of 0.5mg per day in divided doses to a maximum of 15-45mg per day; the control group will receive a placebo similar in size and shape.

Participants/Inclusion and exclusion criteria
Inclusion criteria includes: Meeting the DSM-V diagnostic criteria for opioid use disorder, aging 5-18 years.
Exclusion criteria includes: allergy to buprenorphine and buspirone, having chronic and/or inflammatory diseases, having major psychiatric disorders, lack or revoking of consent by parent or legal guardian.

Intervention groups
The first group will receive buprenorphine 2 to 8 mg according to the protocol and buspirone 0.5 mg per kg in divided doses on the first day, increasing to a maximum dose of 15 to 45 mg per day until the end of the study. People in the second group receive placebo along with buprenorphine from the first day

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

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110411006168N5**
Registration date: **2023-04-29, 1402/02/09**
Registration timing: **registered_while_recruiting**

Last update: **2023-04-29, 1402/02/09**
Update count: **0**

Registration date
2023-04-29, 1402/02/09

Registrant information

Name
Mahin Eslami Shahrbabki

Name of organization / entity
Kerman University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 34 1211 6328

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-10-23, 1401/08/01

Expected recruitment end date
2023-08-23, 1402/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The efficacy of Buspirone on withdrawal symptoms in children and adolescents with substance use disorder on treatment with buprenorphine

Public title
The efficacy of Buspirone on withdrawal symptoms in children and adolescents with substance use disorder on treatment with buprenorphine

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 orBuspirone. .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

- Participant
- Care provider
- Investigator

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)
Double blinded

Blinding description
Buspirone and placebo tablets are completely similar in terms of color and size, and neither the researcher nor the patient will know the type of drug prescribed.

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

City
kerman

Province
Kerman

Postal code
7616913555

Approval date
2022-09-21, 1401/06/30

Ethics committee reference number
IR.KMU.AH.REC.1401.080

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

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, 0.5 mg/kg of buspirone is given to patients in divided doses three times a day, and increased to a maximum dose of 15 to 45 mg per day until the end of the study.

Category

Treatment - Drugs

2

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 have 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. Also, from the first day, they receive a placebo pill of the same shape and size as buspirone.

Category

Placebo

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

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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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Subspecialist
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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