Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 2026

Comparing effects of 4-week treatment of celecoxib and ibuprofen on craving of opioid abusers during the withdrawal period

Protocol summary

Summary

This study is a randomized clinical trial on 30 patients abusing opioids who are candidates for treatment with NSAIDs due to having pain during their withdrawal period. After obtaining ethical approval and written informed consent form, patients will be devided into 2 groups after simple randomization. Subjects in group 1 will receive celecoxib 200 mg per day and participants in group 2 will be assigned to receive 1600 mg ibuprofen per day. 0-10 numeric pain scale and DDQ (Desire for Drug questionaire) are utilized to assess pain and craving of patients, at baseline and at the end of the treatment period (after 4 weeks). Questionnaires will be completed under the supervision of a clinical psychologist; data extraction and analysiswill be performed by a statistician.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201609207202N11**
Registration date: **2016-10-31, 1395/08/10**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-10-31, 1395/08/10

Registrant information

Name

Padideh Ghaeli

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6695 4709

Email address

pghaeli@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-04-10, 1395/01/22

Expected recruitment end date

2017-04-10, 1396/01/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing effects of 4-week treatment of celecoxib and ibuprofen on craving of opioid abusers during the withdrawal period

Public title

Effects of celecoxib versus ibuprofen on craving in opioid abusers during withdrawal period

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age range 18-65; not using other NSAIDs during the trial; having abused opiates for at least six months Exclusion criteria: pregnancy; lactation; suffering serious physical illnesses such as cancer, cardiovascular diseases, respiratory, cerebrovascular diseases and any thyroid disorder including Hypo or hyperthyroidism; People with other axis I psychiatric disorders and intellectual disability.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Pharmaceutical Sciences Research Center of Tehran University of Medical Sciences
Street address
Central building of Tehran University of Medical Sciences, Keshavarz BLVD
City
Tehran
Postal code
Approval date
2016-05-11, 1395/02/22
Ethics committee reference number
IR.TUMS.REC.1395.2584

Health conditions studied

1

Description of health condition studied
Craving
ICD-10 code
F11.3
ICD-10 code description
Mental and behavioural disorders due to use of opioids withdrawal state

Primary outcomes

1

Description
craving
Timepoint
At baseline and 4 weeks after the initiation of the study
Method of measurement
Drug Desire Questionnaire (DDQ)

Secondary outcomes

1

Description
pain
Timepoint
At baseline and 4 weeks after the initiation of the study
Method of measurement
0-10 numeric pain rating scale

2

Description
other side effects of treatments
Timepoint
after 4 weeks of treatment
Method of measurement
Side Effect Check List

Intervention groups

1

Description
celecoxib capsule 200 mg orally daily for 1 month
Category
Treatment - Drugs

2

Description
ibuprofen, soft gel capsule 400 mg four times daily up to 1 month
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Roozbeh Hospital Clinic
Full name of responsible person
Sana Khajehpour
Street address
Roozbeh Hospital, South Kargar Ave
City
Tehran

2

Recruitment center
Name of recruitment center
Tooska cessation camp
Full name of responsible person

Sana Khajehpour

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Vice-Chancellor for Reseach of Faculty of Pharmacy

Street address

Faculty of Pharmacy-Tehran University of Medical Sciences-16th Azar Street-Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Roozbeh Hospital

Full name of responsible person

Doctor Sara Jafari

Position

Doctor of Medicine, Psychology Speciality

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of Pharmacy of Tehran University of Medical Scienses

Full name of responsible person

Doctor Padideh Ghaeli

Position

Doctor of Pharmacy, Clinical Pharmacy Speciality

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

Ms. Sana Khajehpour

Position

Pharm.D Student

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty