Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Clinical Trial on the efficacy of low dose naltrexone vs placebo on pain intensity in Trigeminal Neuralgia and Chronic migraine patients

Protocol summary

Study aim

Determination of the effect of low-dose naltrexone in comparison with guillotine on pain intensity in patients with TN and chronic migraine

Design

The placebo-controlled clinical trial is a single-blind, cross-over that randomly divides 40 patients into two groups by writing the numbers 1 to 40 on balls and placing them in a box. We will give and ask the patient to pick up a ball. If the ball removed by the patient was an odd number, the patient will be in the first group, and if the removed ball shows an even number, the patient will be in the second group. Finally, the ball is removed from the box by the patient and is no longer placed inside the box.

Settings and conduct

It will be performed in the oral and facial pains department of Kerman Dental School in 1401. It will last for eleven weeks for each patient as follows: base line (1 week), placebo (2 weeks) and low-dose naltrexone (8 weeks), the first week no capsule is prescribed as a base line and the patient is asked Will complete your daily report including the VAS form and most pain during the day. Patients will be unaware that they are taking placebo or low-dose naltrexone while taking the drug.

Participants/Inclusion and exclusion criteria

1- According to ICHD3 criteria, they have been diagnosed with TN or chronic headache. 2- Be over 18 years old. 3- Have the necessary cooperation to participate in the study.

Intervention groups

Low-dose naltrexone and placebo to patients with chronic trigeminal neuralgia and migraine pain

Main outcome variables

The rate of recovery of chronic pain in patients; The extent of patients' pain during the day Comparison of pain trends in patients with chronic trigeminal neuralgia and migraine over time in the two groups; Comparison of pain trends in patients with chronic trigeminal neuralgia and migraine over time in two groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171109037332N2**
Registration date: **2022-04-19, 1401/01/30**
Registration timing: **prospective**

Last update: **2022-04-19, 1401/01/30**
Update count: **0**

Registration date

2022-04-19, 1401/01/30

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 32118022

Email address

h.kamyabi1244@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Clinical Trial on the efficacy of low dose naltrexone vs placebo on pain intensity in Trigeminal Neuralgia and Chronic migraine patients

Public title
Evaluation of the effect of low-dose naltrexone in patients with Trigeminal Neuralgia and Chronic migraine patients
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
According to ICHD3 criteria, they are diagnosed with TN or chronic headache. Be over 18 years old Have the necessary cooperation to participate in the study.
Exclusion criteria:
Patient non-cooperation The patient is pregnant or breastfeeding. If the patient uses opioid analgesics or inhales opioids If the patient regularly uses anti-inflammatory drugs. Known allergy or reaction to naltrexone If the patient consumes alcohol and can not refrain from consuming it during the study. The patient has rheumatic or autoimmune diseases The patient has been diagnosed with a mental illness that disrupts his or her collaboration in the study.
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly divided into two groups by placing the numbers 1 to 40 on the balls and placing them in a box and asking the patient to pick up a ball. If the ball removed by the patient was an odd number, the patient will be in the first group, and if the removed ball shows an even number, the patient will be in the second group. Finally, the ball is removed from the box by the patient and is no longer placed inside the box.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, patients are blinded to the period they are taking placebo or medication.
Placebo
Used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kerman University of Medical Sciences
Street address
Kerman school of dentistry, Shafa Ave.
City
Kerman
Province
Kerman
Postal code
7618759689
Approval date
2022-04-18, 1401/01/29
Ethics committee reference number
IR.KMU.REC.1401.023

Health conditions studied

1

Description of health condition studied
Trigeminal Neuralgia
ICD-10 code
G50.0
ICD-10 code description
Trigeminal neuralgia

2

Description of health condition studied
Chronic Migraine
ICD-10 code
G43.7
ICD-10 code description
Chronic migraine without aura

Primary outcomes

1

Description
Low-dose naltrexone, chronic migraine, trigeminal neuralgia
Timepoint
Before the intervention and every day during the intervention
Method of measurement
VAS questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: First two weeks of placebo and then eight weeks of low-dose naltrexalone (4.5 mg) will be given. In the low-dose placebo and naltrexalone phases, the capsules are taken orally daily and the daily symptoms, including the VAS form (zero to 100) and the most pain during the day, will be collected. Low-dose naltrexalone (4.5 mg naltrexone hydrochloride) (co-containing) and placebo alike using standard gelatin capsules and a microcrystalline cellulose filler (Avicel, FMC BioPolymer, Rockland, ME) and a calorie-free sweetener (Will be prepared by a pharmacist). Participants take the capsules (LDN and placebo) once a day for 10 weeks and approximately 1 hour before bedtime (two weeks of placebo capsules and eight weeks of LDN capsules). Patients will be called to the clinic every two weeks to visit and check for their daily symptoms.

Category

Other

2

Description

Intervention group 2: first eight weeks of low-dose naltrexalone (4.5 mg) and then two weeks of placebo. In the low-dose placebo and naltrexalone phases, the capsules are taken orally daily and the daily symptoms, including the VAS form (zero to 100) and the most pain during the day, will be collected. Low-dose naltrexalone (4.5 mg naltrexone hydrochloride) (co-containing) and placebo alike using standard gelatin capsules and a microcrystalline cellulose filler (Avicel, FMC BioPolymer, Rockland, ME) and a calorie-free sweetener (Will be prepared by a pharmacist). Participants take the capsules (LDN and placebo) once a day for 10 weeks and approximately 1 hour before bedtime (two weeks of placebo capsules and eight weeks of LDN capsules). Patients will be called to the clinic every two weeks to visit and check for their daily symptoms.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Oral and facial pain department of Kerman Dental School

Full name of responsible person

Goli Chamani

Street address

Kerman school of dentistry, Shafa Ave.

City

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7618759689

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Email

h.kamyabi1244@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Reza Malekpour Afshar

Street address

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7616913555

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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

Homa Kamyabi

Position

Non-faculty Dentist

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Goli Chamani
Position
professor
Latest degree
Specialist
Other areas of specialty/work
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Medical doctor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Data files entitled "Evaluation of the effect of low-dose naltrexone and placebo on pain intensity in patients with trigeminal neuralgia and refractory migraine after potentially unidentifiable individuals are shared"
When the data will become available and for how long
Start access 6 months after publishing results
To whom data/document is available
The data file can be requested and received by all people, whether working in academia or in industry.
Under which criteria data/document could be used
After requesting and receiving the data file, applicants are allowed to make any use of the documents if asked and allowed by researchers.Individuals can request documentation by email and no conditions are required for their receipt.
From where data/document is obtainable
Individuals can request data documentation by email to Dr. Goli Chamani (golichamani@yahoo.com).
What processes are involved for a request to access data/document
Individuals can email Dr. Goli Chamani (the first person in the article) 6 months after the publication of the results to access the data and documents, and about 1 month later the documents and data will be sent to them.
Comments