

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of low-dose Naltrexone versus placebo in the treatment of chronic plaque psoriasis: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of low-dose Naltrexone versus placebo in the treatment of chronic plaque Psoriasis

Design

This is a double-blind randomized clinical trial, phase II, in which 154 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with chronic plaque Psoriasis who will refer to Sina Hospital in Hamadan City during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded so that neither patients nor the physician who will examine the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 65 years, Chronic plaque psoriasis Exclusion criteria: Pregnancy or breastfeeding, Addiction to opium, Renal or liver failure, History of convulsion, Severe mental disorder

Intervention groups

Intervention group: Routine treatment as well as Naltrexone tablet 4.5 mg before sleep for 12 weeks
Control group: Routine treatment as well as placebo tablet before sleep for 12 weeks

Main outcome variables

Primary outcome: Improvement of the clinical signs of psoriasis
The quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N301**

Registration date: **2019-09-26, 1398/07/04**

Registration timing: **prospective**

Last update: **2019-09-26, 1398/07/04**

Update count: **0**

Registration date

2019-09-26, 1398/07/04

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-12, 1398/07/20

Expected recruitment end date

2020-05-09, 1399/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of low-dose Naltrexone versus placebo in the treatment of chronic plaque psoriasis: a double-blind randomized clinical trial

Public title

Effect of low-dose Naltrexone versus placebo in the treatment of chronic plaque psoriasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age of 18 to 65 years, Chronic plaque psoriasis

Exclusion criteria:
Pregnancy or breastfeeding, Addiction to opium, Renal or liver failure, History of convulsion, Severe mental disorder

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

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **154**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)
Double blinded

Blinding description
The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as triple blind

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences

Street address
Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City
Hamadan

Province
Hamadan

Postal code
6517838695

Approval date
2019-09-14, 1398/06/23

Ethics committee reference number
IR.UMSHA.REC.1398.473

Health conditions studied

1

Description of health condition studied

Psoriasis

ICD-10 code
L40

ICD-10 code description
Psoriasis

Primary outcomes

1

Description

Improvement of the clinical signs of psoriasis

Timepoint

12 weeks after the intervention

Method of measurement

Using Psoriasis Area Severity Index (PASI)

2

Description

The quality of life

Timepoint

12 weeks after the intervention

Method of measurement

Using Dermatology Life Quality Index (DLQI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine treatment as well as Naltrexone tablet 4.5 mg before sleep for 12 weeks

Category

Treatment - Drugs

2

Description

Control group: Routine treatment as well as placebo tablet before sleep for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital in Hamadan City

Full name of responsible person

Dr. Pedram ALirezaei

Street address

Sina Hospital, Mirzadeh Eshghi Ave.

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3827 4184

Email

prc@umsha.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0717

Email

info.research@umsha.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Pedram ALirezaei

Position

Dermatologist

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Phone

+98 81 3827 4184

Email

prc@umsha.ac.ir

Person responsible for updating data

poorolajal@umsha.ac.ir

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

Street address

School of Public Health, Hamadan University of
Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Email

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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