

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Clinical comparison between oral low dose of Naltrexon and standard medication in patients with Frontal Fibrosing Alopecia

Protocol summary

Study aim

Clinical comparison between oral low dose of Naltrexone and standard medication in patients with Frontal Fibrosing Alopecia referred to educational clinics of Isfahan University of Medical Sciences.

Design

The clinical trial includes two treatment groups with parallel groups, single blind, randomized, phase 2-3, on 30 patients, SPSS will use for randomization.

Settings and conduct

This study will conduct as a randomized clinical trial from the spring of 1401 to the end of 1403 in the dermatology clinic of Isfahan Al-Zahra Hospital and other clinics and teaching hospitals affiliated to Isfahan University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- New patients with FFA who have not received any medicine so far 2-Patients who have previously been treated with systemic drugs and have not received systemic drugs in the last one month. Based on clinical and trichoscopic criteria, their disease is active. 3-Patients who are treated with topical medicine and whose disease is still active based on clinical and trichoscopic criteria. Criteria for not entering the study: 1-Pregnancy or breastfeeding 2-History of hypersensitivity to Naltrexone drug 3- Addiction to opium or abuse of opioids 4- Personal or family history of breast cancer

Intervention groups

In this study, patients are divided into two groups. Group1 includes people who will treat with standard and common drugs (finasteride , minoxidil , Pimecrolimus, etc.). Group 2 includes people who will treat with Naltrexone.

Main outcome variables

Prefollicular scale; Interfollicular scale; Erythema; Decline in frontal and temple hair line

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230326057776N1**

Registration date: **2023-04-01, 1402/01/12**

Registration timing: **prospective**

Last update: **2023-04-01, 1402/01/12**

Update count: **0**

Registration date

2023-04-01, 1402/01/12

Registrant information

Name

Fatemeh Azadmanesh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3626 1844

Email address

fatemehazadmanesh95@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical comparison between oral low dose of Naltrexon and standard medication in patients with Frontal Fibrosing Alopecia

Public title

Effects of Naltrexon in patients with Frontal Fibrosing Alopecia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

New patients without any other medications Active status of illness after leaving a systemic medication (at least a month) Active status of illness while the participants are using a topical medication

Exclusion criteria:

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple; Randomization unit: Personal; Randomization tools: SPSS software; All the participants receive a number from 1 to 30. Then they share between two groups of Naltrexon/standard medication by a simple randomization method with SPSS

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients are randomly assigned to one of the two groups of naltrexone treatment and standard treatment, but they do not know which group they are in. The design of study are described for patients.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar-Jarib

Ave, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2022-12-29, 1401/10/08

Ethics committee reference number

IR.MUI.MED.REC.1401.349

Health conditions studied

1

Description of health condition studied

Frontal Fibrosing Alopecia

ICD-10 code

L66.9

ICD-10 code description

Cicatricial alopecia, unspecified

Primary outcomes

1

Description

Pre-follicular scale

Timepoint

Examinations is done at the beginning of the study and then 2, 4 and 6 months later.

Method of measurement

Using Dermoscope

2

Description

Erythema

Timepoint

Examinations is done at the beginning of the study and then 2, 4 and 6 months later.

Method of measurement

Observation

3

Description

Interfollicular scale

Timepoint

Examinations is done at the beginning of the study and then 2, 4 and 6 months later

Method of measurement

Using a dermoscope

4

Description

Decline in frontal and temple hair line

Timepoint

Examinations is done at the beginning of the study and then 2, 4 and 6 months later

Method of measurement

Using a ruler

Secondary outcomes

1

Description

ceasing the progression of disease

Timepoint

Examination is done at the beginning of the study and then 2, 4 and 6 months later.

Method of measurement

Frontal Fibrosing Alopecia Severity Index (FFASI)

Intervention groups

1

Description

Intervention group: Naltrexon

Category

Treatment - Drugs

2

Description

Intervention group: Standard medication

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Fatemeh Azadmanesh

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Shohadaye-Sofe Ave, Al-Zahra Hospital, Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Fariba Iraj

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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

Esfahan University of Medical Sciences

Proportion provided by this source

25

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

Esfahan University of Medical Sciences

Full name of responsible person

Fatemeh Azadmanesh

Position

Resident of Dermatology

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mina Saber

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is a possibility that patients' privacy will be lost.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Person responsible for updating data**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Mina Saber

Position

Assistant Professor

Latest degree