

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Comparison of the effectiveness of white beet leaf spray (*Beta vulgaris*) with placebo in controlling itching and scaling symptoms in dandruff patients

Protocol summary

Study aim

To determine the effect of white beet leaf spray (*Beta vulgaris*) on the symptoms of patients with dandruff

Design

Clinical trial with control group, double-blind, randomized, phase 3 on 210 patients, Block randomization method will be used for randomization.

Settings and conduct

Study place is Touba specialized clinic in Sari; Study population is subjects with dandruff; Type of blinding: double blind in which participant and researcher is not aware of kinds of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with mild to moderate dandruff; Age between 18 and 65 years; Exclusion criteria: pregnancy; lactation; Liver disease; History of severe allergies

Intervention groups

Intervention group: Patients use the usual dandruff medicine (ketoconazole) for 2 weeks and, in addition, they receive 20 puffs of beet leaf spray twice a day, every other day. Control group: Patients take the usual dandruff medicine (ketoconazole) for 2 weeks and, in addition, they receive 20 puffs of placebo spray twice a day, every other day.

Main outcome variables

Scaling; Itching; Inflammation and redness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211225053521N1**

Registration date: **2022-03-15, 1400/12/24**

Registration timing: **prospective**

Last update: **2022-03-15, 1400/12/24**

Update count: **0**

Registration date

2022-03-15, 1400/12/24

Registrant information

Name

Akram Amraei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3324 4893

Email address

a.amraei@ mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-04, 1401/01/15

Expected recruitment end date

2023-03-19, 1401/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of white beet leaf spray (*Beta vulgaris*) with placebo in controlling itching and scaling symptoms in dandruff patients

Public title

The effect of leaf white beet (*Beta vulgaris*) spray on dandruff

Purpose

Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with mild to moderate dandruff Age between 18 and 65 years
Exclusion criteria:
Pregnancy lactation Liver disease History of severe allergies

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **210**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation process will be done with Random allocation software. With this software, 35 blocks of six will be produced and based on this, the samples will be assigned to the groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
The drugs will be given in coded envelopes. 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 double-blind.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1
Ethics committee
Name of ethics committee
Ethic committee of Mazandaran University of Medical Sciences
Street address
Moallem square, Moallem avenue
City
Sari

Province
Mazandaran
Postal code
48168-95474

Approval date
2022-02-08, 1400/11/19
Ethics committee reference number
IR.MAZUMS.REC.1400.684

Health conditions studied

1
Description of health condition studied
Seborrhoea
ICD-10 code
L21.0
ICD-10 code description
Seborrhea capitis

Primary outcomes

1
Description
Scaling
Timepoint
Before the intervention, days 6, 10, 15, and 15 and 30 days after the intervention.
Method of measurement
Adherent scalp flaking score

2
Description
pruritus
Timepoint
Before the intervention, days 6, 10, 15, and 15 and 30 days after the intervention.
Method of measurement
Excoriation Pruritus Grading

3
Description
Inflammation and redness of the head
Timepoint
Before the intervention, days 6, 10, 15, and 15 and 30 days after the intervention.
Method of measurement
Grading method from 0 (none) to 4 (very severe)

Secondary outcomes

1
Description
Patients' satisfaction with treatment
Timepoint
Before the intervention, days 6, 10, 15, and 15 and 30 days after the intervention.
Method of measurement

It is checked by asking and giving points from zero to 100.

Intervention groups

1

Description

Intervention group: In this study, patients will be treated routinely (ketoconazole shampoo) for 2 weeks, and in addition, every other day, they use a herbal beet leaf extract spray 20 puffs twice a day.

Category

Treatment - Drugs

2

Description

Control group: In this study, patients will be treated routinely (ketoconazole shampoo) for 2 weeks, and in addition, every other day, they use a placebo spray 20 puffs twice a day.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Baghban Subspecialty Clinic (Touba)

Full name of responsible person

Dr Assie Jokar

Street address

Khazar Bolvd.

City

Sari

Province

Mazandaran

Postal code

4811573397148

Phone

+98 11 3324 0002

Email

a.jokar@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Majid Saidi

Street address

Deputy of Research and Technology; Mazandaran University of Medical Sciences; Moalem Ave.; Moalem Square

City

Sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3325 7230

Email

pajhooheshi@mazums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Assie Jokar

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

Center for Traditional Medicine and Complementary Medicine of Mazandaran University; Khazar Boulevard, Khazar Square

City

Sari

Province

Mazandaran

Postal code

48168-95475

Phone

+98 11 3324 3117

Email

a.jokar@mazums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Assie Jokar

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

Center for Traditional Medicine and Complementary
Medicine of Mazandaran University; Khazar
Boulevard, Khazar Square

City

Sari

Province

Mazandaran

Postal code

48168-95475

Phone

+98 11 3324 3117

Email

a.jokar@mazums.ac.ir

Center for Traditional Medicine and Complementary
Medicine of Mazandaran University; Khazar
Boulevard, Khazar Square

City

Sari

Province

Mazandaran

Postal code

48168-95475

Phone

+98 11 3324 3117

Email

akramamraei2020@gmail.com

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

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Akram Amraei

Position

Persian Medicine Student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address