Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Preparation and Clinical Evaluation Of Efficacy Of Anti-dandruff Herbal Shampoo In Comparison With Ketoconazole

Protocol summary

Study aim

The aim of this study is to determine the Effectiveness of topical formulation on reducing dandruff symptoms

Design

Two arm parallel double blinded randomised clinical trial phase 2-3 with 2 groups; Control group and Intervention group.

Settings and conduct

All patients referred to medical office of Ahvaz, Iran, who have inclusion criteria were assigned randomly in one of the treatment methods for 4 weeks. These patients randomly receive a bottle containing a herbal formulation or drug.Unique codes, which is generated by the software, will be used on the drug boxes. During the research, the randomization list is held by the statistic consultant.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Presence of dandruff; age between 18 to 60 years; written census to participate in the study. Exclusion criteria: To have any history of hypersensitivity to Azol' s or anti-fungal drugs; Age less than 18 or above 60; Pregnancy or breast feeding; Having liver diseases or Porphyria; Alcohol addiction; History of skin cancer; Consumption any immunosuppressive drug 4 weeks before the study and steroids 2 weeks before study.

Intervention groups

Intervention: Herbal solution ; First washing head for 3 min. with 40 ml of solution then rinse and wash the head by shampoo (keeping the foam for 3 min) once every 3 days for 10 days. After that repeating the process once every 4 days for another 20 days. Control group: Ketoconazol (2%) shampoo; First washing head for 3 min. with 40 ml of solution then rinse and wash the head by shampoo (keeping the foam for 3 min) once every 3 days for 10 days. After that repeating the process once every 4 days for another 20 days.

Main outcome variables

Inflammation and Saling score of head

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181026041466N2**
Registration date: **2019-05-23, 1398/03/02**
Registration timing: **prospective**

Last update: **2019-05-23, 1398/03/02**
Update count: **0**

Registration date

2019-05-23, 1398/03/02

Registrant information

Name

Ali Aghaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3333 8149

Email address

ali.aghaei110@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-05, 1398/03/15

Expected recruitment end date

2019-09-06, 1398/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Preparation and Clinical Evaluation Of Efficacy Of Anti-dandruff Herbal Shampoo In Comparison With Ketoconazole

Public title
Preparation and Clinical Evaluation Of Efficacy Of Anti-dandruff Herbal Shampoo In Comparison With Ketoconazole

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Presence of dandruff age between 15 to 50 years written census to participate in the study

Exclusion criteria:

Age
From **15 years** old to **50 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
For randomization, the permuted block randomization will be used with quadruple blocks. blocks will be produced by using the online site (www.sealedenvelope.com)

Blinding (investigator's opinion)
Double blinded

Blinding description
Unique codes, which is generated by the software, will be used on the drug boxes. By entering each individual into the study based on the produced sequence, the drug box in which the code is registered, will be assigned to the individual. During the research, the randomization list is held by the statistic consultant, and the participants, the project implementer and all those who participate in the measurement of the indicators will not be aware of the assigned groups

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan Road

City
Ahvaz

Province
Khouzestan

Postal code
-61357-15794

Approval date
2019-05-18, 1398/02/28

Ethics committee reference number
IR.AJUMS.REC.1398.164

Health conditions studied

1

Description of health condition studied
Dandruff

ICD-10 code
Seborrhoea

ICD-10 code description
L-21.0

Primary outcomes

1

Description
Inflammation and redness of skulp

Timepoint
Before intervention, 4th weeks after start of intervention and 4 weeks after end of intervention.

Method of measurement
Observation and physical exam

2

Description
Scaling score

Timepoint
Before intervention, 4th weeks after start of intervention and 4 weeks after end of intervention.

Method of measurement
Observation and physical exam

Secondary outcomes

1

Description
Drug side effects

Timepoint
During the study

Method of measurement
Patients' report

Intervention groups

1

Description
Intervention group: Herbal shampoo; First washing head for 3 min. with 40 ml of solution then rinse and wash the head by shampoo (keeping the foam for 3 min) once every 3 days for 10 days. After that repeating the process once every 4 days for another 20 days.
Category
Treatment - Drugs

2

Description
Control group: Washing with Ketoconazol (2%) shampoo; First washing head for 3 min. with 40 ml of solution then rinse and wash the head by shampoo (keeping the foam for 3 min) once every 3 days for 10 days. After that repeating the process once every 4 days for another 20 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
مطب خصوصی
Full name of responsible person
فاروق آقایی
Street address
koote abdollah
City
Ahvaz
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Khouzestan
Postal code
6135733184
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+98 61 3336 8149
Email
ali.aghaei110@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Dr.Mohammad Badavi
Street address
Ahvaz Jundishapur University of medical Sciences, Golestan road.
City
Ahvaz
Province
Khouzestan
Postal code
6135733184
Phone
+98 61 3336 2414
Email
Badavim@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Ali Aghaei
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
Medical Pharmacy
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Ali Aghaei
Position

Student

Latest degree

A Level or less

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

Student

Latest degree

A Level or less

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Email

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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

Only a part of the data will be shared

When the data will become available and for how long

The access period will be 6 months after the publication of the results

To whom data/document is available

Six months after the publication of this study papers, the obtained data will be available to the applicant researchers for further analysis

Under which criteria data/document could be used

Six months after the publication of this study papers, the obtained data will be available to the applicant researchers for further analysis

From where data/document is obtainable

Applicants can be contacted with corresponding author by e-mail

What processes are involved for a request to access data/document

Applicants will be able to access the obtained data from current study by sending an email to the corresponding author up to one month

Comments