

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Evaluation of the effect and safety of herbal extracts anti dandruff formulation comparing with clotrimazole lotion in patients with seborrheic dermatitis referring to the clinic of center for research and training in skin diseases and leprosy during the year 1394

Protocol summary

Summary

In this randomized double blind phase 2 clinical trial control study with placebo, the efficacy and safety of anti-dandruff formulation containing herbal extracts comparing with clotrimazole lotion in patients with seborrheic dermatitis will be evaluated. 20 young men aged 20-30 years, referred to dermatology clinic of Center For Research And Training In Skin Diseases And Leprosy, with clinically diagnosed seborrheic dermatitis by dermatologist, with negative history of consumption of topical antifungals and topical steroids during the last 2 weeks, and without any comorbidities such as AIDS and parkinson disease,.... will be enrolled in our study. Patients randomly divided into two groups, after signing the consent form. The first group will use anti-dandruff formulation containing herbal extracts and the second group will use clotrimazole lotion. They use the lotions twice a day for 4 weeks. Dandruff severity, amount of scalp sebum and scalp PH evaluated before treatment, 2 weeks and 4 weeks after treatments and then the data will be analyzed. The amount of scalp sebum will be evaluated by the sebumeter. The PHmeter will be used for evaluating the scalp PH. Dandruffmeter will be used for analyzing the size and severity of dandruff. For comparing the effect of herbal extract formulation with clotrimazole lotion, the results of scalp PH, sebum secretion and size and severity of scalp dandruff will be analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015012520802N1**

Registration date: **2015-08-15, 1394/05/24**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-08-15, 1394/05/24

Registrant information

Name

Hamid reza Ahmadi Ashtiani

Name of organization / entity

Islamic Azad university of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2278 2576

Email address

ahmadi@iaups.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Islamic Azad University
Pharmaceutical Branch of Tehran

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect and safety of herbal extracts anti dandruff formulation comparing with clotrimazole lotion in patients with seborrheic dermatitis referring to the clinic of center for research and training in skin diseases

and leprosy during the year 1394

Public title

Herbal extract solution in treatment of seborrheic dermatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: male patients; healthy general condition; clinically diagnosed seborrheic dermatitis; 20-30 years old; consent form signed by patients.
Exclusion criteria: use of topical steroids during 2 weeks ago; use of topical retinoids during 2 weeks ago; use of topical antifungals during 2 weeks ago; use of topical anti-inflammatory drugs during 2 weeks ago; use of topical antibiotics and any other topical treatments for seborrheic dermatitis like anti-dandruff shampoo and coal tar during 2 weeks ago; use of systemic anti-fungals during the last month; use of systemic steroids during the last month; use of systemic antibiotic during the last month; use of systemic anti-inflammatory drugs and immunomodulator drugs during the last month; use oral retinoid during last 6 months; history of hypersensitivity to azoles or herbal compound of our solution; comorbidities(AIDS,Parkinson,diabetes,...); skin disease like psoriasis, acne, ...

Age

From **20 years** old to **30 years** old

Gender

Male

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of centre for research and training in skin disease and leprosy

Street address

415,Taleghani st

City

Tehran

Postal code**Approval date**

2015-04-18, 1394/01/29

Ethics committee reference number

27533

Health conditions studied**1****Description of health condition studied**

Seborrheic Dermatitis

ICD-10 code

L21.8

ICD-10 code description

Other seborrheic dermatitis

Primary outcomes**1****Description**

Scalp sebum

Timepoint

Beginning of the study, 2 weeks and 4 weeks after starting the treatment

Method of measurement

Sebometer

2**Description**

Scalp PH

Timepoint

Beginning of the study, 2 weeks and 4 weeks after starting the treatment

Method of measurement

PH meter

3**Description**

Dandruff

Timepoint

Beginning of the study, 2 weeks and 4 weeks after starting the treatment

Method of measurement

Pixel

Secondary outcomes**1****Description**

Erythema and itching

Timepoint

Beginning of the study, 2 weeks and 4 weeks after treatment

Method of measurement

Clinical examination, Questionnaire

Intervention groups

1

Description

Volunteers in the intervention group use the anti dandruff lotion with herbal extracts twice a day for 4 weeks, 1 cc per consumption topical on their scalp

Category

Treatment - Drugs

2

Description

Volunteers in the control group use clotrimazole lotion 1 cc twice daily for 4 weeks, topically on their scalp

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Center For Research and Training in Skin Diseases and Leprosy

Full name of responsible person

Dr. Azin Ayatollahi

Street address

415, Taleghani street, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Islamic Azad University
Pharmaceutical Branch of Tehran

Full name of responsible person

Dr Afsaneh Arbabi

Street address

Pharmaceutical Sciences Branch of Islamic Azad
University, Yakhchal st, Shariati Ave.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Islamic Azad University
Pharmaceutical Branch of Tehran

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Pharmaceutical Sciences Branch of Islamic Azad
University

Full name of responsible person

Dr Hamid Reza Ahmadi Ashtiani

Position

Assistant Professor

Other areas of specialty/work

Street address

Pharmaceutical Sciences Branch of Islamic Azad
University, Yakhchal St, Shariati Ave.

City

Tehran

Postal code

Phone

+98 21 2264 0051

Fax

Email

ahmadi@iaups.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Pharmaceutical Sciences Branch of Islamic Azad
University

Full name of responsible person

Dr Hamid Reza Ahmadi Ashtiani

Position

Assistant Professor

Other areas of specialty/work

Street address

Pharmaceutical Sciences Branch of Islamic Azad
University, Yakhchal St, Shariati Ave.

City

Tehran

Postal code

Phone

+98 21 2248 0233

Fax

Email

ahmadi@iaups.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

Narges Bidhendi

Position

Pharmacology student

Other areas of specialty/work**Street address**

16 Toranj Ally, Eftekharian St, Azadi Ave, Heravi Sq

City

Tehran

Postal code

1669837611

Phone

+98 21 2295 4828

Fax**Email**

narges.bidhendi@gmail.com

Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty