

# 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

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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##### Full name of responsible person

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**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*