

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

**evaluation the efficacy of itrifal saghir on head sebum production in seborrheic patients referring to dermatology clinic of tehran imam khomeiny hospital in comparison with placebo .**

### Protocol summary

#### Study aim

Oral intake of the herbal prebiotic "Triphala" may be effective in reducing scalp seborrhea.

#### Design

An 8-week randomized, patient- and outcome assessor-blinded, placebo-controlled intervention trial was conducted. 94 eligible patients were randomized into two groups.

#### Settings and conduct

trial was conducted from 2 June to 13 December 2015 at the dermatology clinic of the Skin and Stem Cell Research Center, Tehran, Iran. Participants were patients with scalp seborrhea aged 14 to 50 years.it was a randomized, patient- and outcome assessor-blinded, placebo-controlled intervention.Scalp sebum levels were analyzed using Sebumeter® sm 815.

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: complaining of scalp oiliness, objectively confirmed by a trained physician. 14 to 50 years old Exclusion criteria: any symptoms of seborrheic dermatitis, had used systemic corticosteroid, anti-fungal, isotretinoin, or contraceptive medications in the 4 weeks prior to the study, or had used topical corticosteroid or antifungal shampoos or solutions in the two weeks prior to the study. Patients with a history of autoimmune disease or any type of cancer and those who were pregnant or lactating were also excluded.

#### Intervention groups

8 weeks with twice a day capsules containing 1 g of the herbal combination Triphala (standardized as 234.2 mg polyphenols per 1 g Triphala) or a placebo (wheat flour).

#### Main outcome variables

changing in scalp sebum levels ( $\mu\text{g}/\text{cm}^2$ )

### General information

#### Reason for update

Correction of sample size and contact information

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT2014070218332N1**

Registration date: **2015-06-17, 1394/03/27**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-10-26, 1398/08/04**

Update count: **1**

#### Registration date

2015-06-17, 1394/03/27

#### Registrant information

##### Name

Elham Zareie

##### Name of organization / entity

Shahid Sadoughi University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2227 9276

##### Email address

zareiehms1@gmail.com

#### Recruitment status

**Recruitment complete**

#### Funding source

Vice Chancellor for research, Shahid Sadoughi University of Medical Sciences

#### Expected recruitment start date

2015-06-02, 1394/03/12

#### Expected recruitment end date

2015-12-13, 1394/09/22

#### Actual recruitment start date

2015-06-02, 1394/03/12

#### Actual recruitment end date

2015-12-13, 1394/09/22

#### Trial completion date

**Scientific title**

evaluation the efficacy of itrifal saghir on head sebum production in seborrheic patients referring to dermatology clinic of tehran imam khomeiny hospital in comparison with placebo .

**Public title**

effect of itrifal saghir on scalp seborrhea

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

inclusion criteria:patients aged 14 to 50 years suffering from scalp seborrhea. scalp oiliness was objectively confirmed by a trained physician.

**Exclusion criteria:**

pregnancy breast feeding patients with auto immune disease patients with any kind of cancer presence of seborrheic dermatitis sings on head using oral and topical drugs for treating seborrhea from 4 and 2 weeks before joining the research.

**Age**

From **14 years** old to **50 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **94**

Actual sample size reached: **91**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

A randomization sequence block was generated by computer using balanced block-of-four.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The generated random sequence was coded by anonymous codes so that the patient allocation process would be concealed into two groups. Due to the similarity of the inactive substance capsules in the case group, the patients remained unaware by their allocation to the treatment groups. Also the outcome assessor was not aware of groups' allocation.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics Committee,Yazd Shahid Sadoughei Univesity of Medical Sciences

**Street address**

Central department of Shahid Sadoughei Medical University, Shahid bahonar squer, Yazd

**City**

yazd

**Province**

Yazd

**Postal code**

8916978477

**Approval date**

2014-06-28, 1393/04/07

**Ethics committee reference number**

IR.SSU.REC.1393.65406

**2****Ethics committee****Name of ethics committee**

کمیته اخلاق دانشگاه علوم پزشکی تهران

**Street address**

Research and Technology center, Sixth Floor, Qods Ave., Keshavarz Blvd.

**City**

Tehran

**Province**

Tehran

**Postal code**

1417653761

**Approval date**

2016-01-06, 1394/10/16

**Ethics committee reference number**

IR.TUMS.REC.1394.1574

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

scalp seborrhea

**ICD-10 code**

L21.0

**ICD-10 code description**

seborrhea capitis

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

The sebum level of the scalp measured by sebumeter sm 815

**Timepoint**

0-week 4-week 8

**Method of measurement**

## Secondary outcomes

### 1

#### Description

Participants' overall satisfaction with the treatment process was rated at the end of the study on a scale from 0=very poor to 100=very good.

#### Timepoint

At the end of the study

#### Method of measurement

It was rated on a scale from 0=very poor to 100=very good.

## Intervention groups

### 1

#### Description

Placebo:wheat flour.Filled in 1 gr capsules.8 weeks

#### Category

Treatment - Drugs

### 2

#### Description

drug:Triphala.Filled in 1gr capsules.8 weeks

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dermatology clinic of skin & stem cell research center depended to Tehran university of medical sciences

##### Full name of responsible person

Elham Zareie

##### Street address

Tehran Province, Tehran, No 4 Maryam Dead End South Andarzgo Blvd. Kamraniyeh

##### City

Tehran

##### Province

Tehran

##### Postal code

1937957511

##### Phone

+98 21 2221 5558

##### Fax

+98 21 2221 5558

##### Email

afasaneh.najafi@yahoo.com

##### Web page address

<http://skinstemcell.ir>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Sadougei University of Medical Sciences

##### Full name of responsible person

Dr. Fatemeh Ezoddini

##### Street address

Central Building of Shahid Sadougei Medical University, Shahid Bahonar square, Yazd

##### City

Yazd

##### Province

Yazd

##### Postal code

8913893111

##### Phone

+98 35 3312 3222

##### Email

mosavi\_yazddent@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Shahid Sadougei 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

Shahid Sadougei University of Medical Sciences

##### Full name of responsible person

Dr.Elham Zareie

##### Position

PhD student of Persian medicine

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Traditional Medicine

##### Street address

Tehran Province, Tehran, No 4 Maryam Dead End South Andarzgo Blvd. Kamraniyeh

##### City

Tehran

##### Province

Tehran

##### Postal code

1937957511

**Phone**

009822279276

**Fax**

**Email**

zareiehms1@gmail.com

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Skin & Stem cell Research Center

**Full name of responsible person**

Dr.Parvin Mansouri

**Position**

Professor of Tehran University of medical sciences.  
dermatologist

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

**Street address**

Tehran.Sadr Ave.kamranieh street.maryamalley

**City**

Tehran

**Province**

Tehran

**Postal code**

1937957511

**Phone**

+98 912 124 1636

**Fax**

**Email**

mansouripr@yahoo.com

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Shahid Sadoughi University of Medical Sciences

**Full name of responsible person**

Dr.Elham Zareie

**Position**

PhD student of Persian medicine

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Traditional Medicine

**Street address**

Tehran Province, Tehran, No 4 Maryam Dead End

South Andarzgo Blvd. Kamraniyeh

**City**

Tehran

**Province**

Tehran

**Postal code**

1937957511

**Phone**

+98 21 2227 9276

**Fax**

+98 21 2267 2972

**Email**

zareiehms1@gmail.com

**Web page address**

## 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**

Yes - There is 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

**Title and more details about the data/document**

Information about the main outcome can be shared after Unrecognizable

**When the data will become available and for how long**

After printing the results in paper form

**To whom data/document is available**

Researchers working in academic institutions

**Under which criteria data/document could be used**

Analysis similar to that used in the paper or supplement

**From where data/document is obtainable**

Elham Zareie zareiehms1@gmail.com

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

After considering no contradiction with research ethics for up to 3 months

**Comments**