

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

sebumeter sm 815- unit: µg/cm²

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 Unrecognizabling

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