

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### Assessment of the effects of oral whey protein (an Iranian Traditional Medicine product) on improvement of mild to moderate skin lesion of psoriasis in comparison with placebo

#### Protocol summary

##### Summary

The aim of this study is to evaluate the effect of whey protein on improvement of mild to moderate skin lesions on psoriasis sufferers. This study is a randomized / phase 2/ triple-blind clinical trial. The important criteria: The patients having under 10 percent of skin lesion: The patients suffering from stable plaque psoriasis. The criteria that impede patients from entering the study: allergy to lactose: The patients suffering from uncontrolled cardiovascular and urinary and hematological and respiratory diseases: those have had known cancer and cancer history in the last 5 years: those suffering from metabolic disease: those have metabolic diseases and water and electrical imbalance and infection: past history of suffering from kidney stone disease: age under 18 and above 70 years old. The studied population: patients above 18 years old suffering from mild to moderate psoriasis that have the criteria for entering the study and who have tendency to participate in the study. In this study 90 patients will enter in two intervention and control groups. The intervention group will receive whey protein with emollient ointment (20% glycerin) that (the patient was taking before the study) and the control group will receive placebo (lactose) and emollient ointment. Both groups will be synchronized on demographic data and topical ointment. The intervention group dissolve 10 grams of whey protein in a cup of warm water and when fasting in the morning they drink one third of cup every 15 minutes. The control group will receive placebo in the same way. Duration of consumption is 12 weeks. The primary outcomes of the study are: disease severity, extent of lesion, quality of life and severity of itching.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015100524359N1**

Registration date: **2015-11-13, 1394/08/22**

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

Last update:

Update count: **0**

##### Registration date

2015-11-13, 1394/08/22

##### Registrant information

###### Name

Akramosadat Atyabi

###### Name of organization / entity

School of Traditional Medicine of Tehran University of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 22988551

###### Email address

a-atyabi@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2015-11-06, 1394/08/15

##### Expected recruitment end date

2016-02-04, 1394/11/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Assessment of the effects of oral whey protein (an Iranian Traditional Medicine product) on improvement of mild to moderate skin lesion of psoriasis in comparison with placebo

**Public title**

Assessment of the effects of whey protein on psoriasis

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: patients above 18 years old ;skin involvement under 10 percent ;stable plaque psoriasis (which have been stable in extent and severity for at least 2 months) ; patients who haven't been using psoralen for the past 28 days and UVB for the past 30 days ; patients who haven't participated in any studies in the last month;patients who consent on participating in the study. The criteria that impede patients from entering the study : age under 18 and above 70 years old ;Patients suffering from other kinds of psoriasis like pustular, erythrodermic, or palmoplantar or psoriatic arthritis or patient having their face involved;skin involvement more than 10 percent ; past history of allergy to lactose ;patients suffering from the kidney stone disease; patients who use drugs that intensify psoriasis e.g.Beta blockers .NSAIDs.Antimalarials .Terbinafine.Ca channel blockers.Interleukins and Lithium ;Oral corticosteroids or immunosuppressants consumption during the 4 weeks prior to baseline ;pregnancy and lactation ;The patients suffering from uncontrolled cardiovascular and respiratory and hematological and urinary diseases ;those who have known cancer and cancer history in the last 5 years, those have metabolic diseases and water and electrical imbalance and infection; any record of allergy ; acute sensitivity and progressive form of disease and tendency to erythrodermy ;patients who must use systemic psoriasis drugs; patients are dissatisfaction with participating in the study . The criteria that lead to the exclusion of the patients who were participating in the study : skin events after taking the drug during the study ; infection on the lesion during the study ; patients getting pregnant during the study ; patient suffering from the kidney stone disease during the study.

**Age**

From **18 years** old to **70 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

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

Triple blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

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

empty

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

Tehran University of Medical Science

**Street address**

Tehran University of Medical Science, Ghods street, Enghelabe Eslami street, Tehran, Iran

**City**

Tehran

**Postal code**

1417614411

**Approval date**

2015-09-29, 1394/07/07

**Ethics committee reference number**

IR.TUMS.REC.1394.859

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

Psoriasis

**ICD-10 code**

L40.0

**ICD-10 code description**

Plaque psoriasis

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

Severity

**Timepoint**

At baseline -end of 8 and 12 weeks

**Method of measurement**

psoriasis activity and severity index

**2****Description**

Extent of the lesion

**Timepoint**

At baseline -end of 8 and 12 weeks

**Method of measurement**

BODY SURFACE AREA

**3****Description**

quality of life

**Timepoint**

At baseline -end of 12 weeks

**Method of measurement**

persian valid version of Dermatology of life and quality index

**4**

**Description**

Intensity of pruritis

**Timepoint**

At baseline -end of 8 and 12 weeks

**Method of measurement**

VISUAL analog Scale

**Secondary outcomes**

**1**

**Description**

Evaluation of Possible gastrointestinal and skin complications

**Timepoint**

End of 8 and 12 weeks

**Method of measurement**

CTCAE) common terminology for Adverse Event v40.2009)

**2**

**Description**

The photography of lesion

**Timepoint**

At baseline-end of 8 and 12 weeks

**Method of measurement**

The camera with 10 mega pixel sensor accuracy specifications .Canon EOS 400D Lens EFS18-55mm

**Intervention groups**

**1**

**Description**

The control group dissolve 10 gram of placebo(200 g=lactose and 100 g sugar )in a cup of warm water and when fasting they drink one third of cup every 15 minute.Meanwhile they will continue emollient ointment that have used before study .

**Category**

Placebo

**2**

**Description**

The intervention group dissolve 10 gram of whey protein in a cup of warm water and when fasting they drink one third of cup every 15 minute .Meanwhile they will continue emollient ointment that have used before study .

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Skin Clinic of Imam Khomeini

**Full name of responsible person**

Dr.Parvin Mansouri

**Street address**

Imam Khomeini Hospital , The end of Keshavarz Blvd

**City**

Tehran

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Science

**Full name of responsible person**

Leila shirbeigi

**Street address**

No.67, West jamali alley, Vafamanesh street , Heravi square, Pasdaran , Tehran

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Tehran University of Medical Science

**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**

School of Traditional Medicine ,Tehran University of Medical Science,Tehran,Iran

**Full name of responsible person**

Akromosadat atyabi

**Position**

Assistant of traditional medicine

**Other areas of specialty/work**

**Street address**

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

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## Person responsible for updating data

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School of Traditional Medicine ,Tehran University of Medical Science,Tehran,Iran

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## 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*