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 randomize / 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 patient will enter in two intervention and control group.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 Possibe 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

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

City

Tehran
Postal code
1668753963
Phone
+98 21 2298 8551
Fax
+98 22988551222
Email
a-atyabi@razi.tums.ac.iraatyabi113@gmail.com
Web page address
www.itm.tums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
School of Traditional Medicine ,Tehran University of Medical Science,Tehran,Iran
Full name of responsible person
Akramosadat atyabi
Position
Assistant of traditional medicine
Other areas of specialty/work
Street address
No.67، West jamali alley، Vafamanesh street، Heravi square، Pasdaran ، Tehran
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Phone
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Fax
+98 22988551222
Email
a-atyabi@razi.tums.ac.iraatyabi113@gmail.com
Web page address
www.itm.tums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
School of Traditional Medicine ,Tehran University of Medical Science,Tehran,Iran
Full name of responsible person
Akramosadat atyabi
Position
Assistant of traditional medicine
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Web page address
www.itm.tums.ac.ir

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