

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Evaluation of efficacy of whey protein in improving the symptoms of patients with contact dermatitis: A randomized double blind placebo, control clinical trial

Protocol summary

Study aim

Determine the effectiveness of whey protein in improving the symptoms of patients with contact dermatitis

Design

A randomized double blind placebo - control clinical trial

Settings and conduct

60 patients over 5 years of age with Contact dermatitis referred to the clinics of Shiraz University of Medical Sciences will be studied, divided into two groups of 30 patients treated with drug and placebo. Patients will receive 30 grams of whey protein powder per day. During the intervention, the examination and the questionnaire (SCORAD and DLQ index (dermatology life quality index)) will be performed at the beginning of the treatment also in the second week and 4th week and the results will be reviewed.

Participants/Inclusion and exclusion criteria

Age over 5 years Contact dermatitis (clinical or with patch test) Cows milk allergy Pregnancy or severe disease as malignancy Patients who had a new treatment or an increase in the dose within 4 weeks prior to the intervention Patients treated with immunosuppressive drugs

Intervention groups

Patients will receive 30 grams of powder per day from reputable pharmaceutical companies. During the intervention, the examination and the questionnaire (SCORAD and DLQ index (dermatology life quality index)) will be performed at the beginning of the treatment also in the second week and 4th week and the results will be reviewed.

Main outcome variables

Determine the effectiveness of whey protein in improving the symptoms of patients with contact dermatitis including control of cutaneous dryness, itching, erythema, swelling, eczema and lichenification.

General information

Reason for update

Modify the start and end dates of patient admissions

Acronym

IRCT registration information

IRCT registration number: **IRCT20190202042587N1**

Registration date: **2019-03-03, 1397/12/12**

Registration timing: **prospective**

Last update: **2020-08-09, 1399/05/19**

Update count: **2**

Registration date

2019-03-03, 1397/12/12

Registrant information

Name

Seyyed Mohammad Hashemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3612 5401

Email address

smhashemi5@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-06, 1397/12/15

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of efficacy of whey protein in improving the symptoms of patients with contact dermatitis: A randomized double blind placebo, control clinical trial

Public title

Evaluation of efficacy of whey protein in contact dermatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 5 years Contact dermatitis(clinical or with patch test)

Exclusion criteria:

Cows milk allergy Pregnancy or severe disease as malignancy Patients who had a new treatment or an increase in the dose within 4 weeks prior to the intervention Patients treated with immunosuppressive drugs

Age

From **5 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The study will be blind for patient, outcome assessor and statistical analyzer. Drug and placebo bottles before filling in according to the randomized block table are divided into two equal groups of 30 digits and then, based on the results, bottles are filled with drugs or placebo. The only researcher based on the primary form of the stored results can decode the content of each bottle. None of the responsible person will be aware of the encoding. Results of control and intervention groups under the heading of group A and B delivered to the statistical analyst.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patient, outcome assessor and statistical analyzer

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Zand Blvd., Shiraz University of Medical Sciences

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2018-12-19, 1397/09/28

Ethics committee reference number

IR.SUMS.MED.REC.1397.383

Health conditions studied

1

Description of health condition studied

Contact dermatitis

ICD-10 code

L25

ICD-10 code description

Unspecified contact dermatitis

Primary outcomes

1

Description

Reduced scores in questionnaire and during periodic examination, which indicate better control of the disease and reduced symptoms

Timepoint

At the beginning of the study, 14 and 28 days after starting the drug

Method of measurement

Questionnaire including EASI (eczema area and severity index) and VAS (visual analog scale) and DLQ index (dermatology life quality index)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients will receive 30 grams of

powder per day, orally, from reputable pharmaceutical companies(half the dose in children) divided into two equal doses.

Category

Treatment - Drugs

2**Description**

Control group: Patients will receive 30 grams of placebo per day (half the dose in children), divided into two equal doses, orally. The placebo is made up of 6-1-1 from corn starch, corn flour and lactose which is very similar to Whey in smell and taste and lacks harmful effects.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Reza clinic(Namazi Hp.)

Full name of responsible person

Seyyed Mohammad Hashemi

Street address

Namazi Square

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Youness Ghasemi

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Seyyed Mohammad Hashemi

Position

Fellowship

Latest degree

Specialist

Other areas of specialty/work

Allergy & clinical immunology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Seyyed Mohammad Hashemi
Position
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Latest degree
Specialist
Other areas of specialty/work
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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

Undecided - It is not yet known if there will be 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