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

City

Shiraz

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71348714737

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Email

emamreza@sums.ac.ir

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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Zand Blvd.,Shiraz University of Medical Sciences

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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

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Position

Fellowship

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact
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Shiraz University of Medical Sciences
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Seyyed Mohammad Hashemi
Position
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Latest degree
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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