Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Nov 2026

Effect of soy protein Isolate and flaxseed oil on inflammation, oxidative stress parameters and Wound healing in burn patients

Protocol summary

Summary

The purpose of this study was to investigate the effect of isolated soy protein and flaxseed oil on hematological parameters, inflammation, oxidative stress, nutritional status and clinical burns. Sampling is based on convenience sampling and collect of available hospital inpatients in Qutb al-Din Shirazi Burn hospital. Random assignment of subjects is based on permutation block technique And with regard to the inclusion and exclusion criteria. Inclusion and exclusion Criteria : People age 15 to 60 years, burn surface area of 20% -50%, acceptance period maximum to 24 to 48 hours and not having liver disease, renal disease, and not being pregnant or lactating mothers. Sample was considered to have 69 members. Patients are divided in to three groups of intervention: 1 - cookies made with soy protein isolate and flaxseed oil, 2 - cookies made from isolated soy protein and corn oil and 3 - cookies made from wheat flour and corn oil . Cookies made by the cooking workshop without patient awareness of the types of materials. Blood samples will take before and 3 weeks after the intervention and urine samples will be collected and indicators hs-CRP, SOD, MDA , Ferritin and Urinary nitrogen excretion is measured. To assess the nutritional and clinical status of patients, respectively, a nutritional questionnaire designed and stereology software is used.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014051817740N1**
Registration date: **2014-06-27, 1393/04/06**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-06-27, 1393/04/06

Registrant information

Name
Abdollah Hozhabrimanesh
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2014-06-21, 1393/03/31

Expected recruitment end date

2014-12-21, 1393/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of soy protein Isolate and flaxseed oil on inflammation, oxidative stress parameters and Wound healing in burn patients

Public title

Effect of soy protein Isolate and flaxseed oil in burn patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criterias : People aged15-60 years ; Willingness

to cooperate ; People with body surface area between 20% -50% ; oral nutrition ; During peak of burn admissions 24-48 hours Exclusion Criterias : Having an allergy to soy ; consumtion of omega-3 during the previous week or month ; having kidney disease(Dialysis),having liver disease ; Pregnant and lactating women ; Excessive hemorrhage ; Having a weight loss greater than 10% within 6 months prior to admission ; BMI(body mas index)<18, BMI>30 kg/m2 ; Failure to adhere to consume at least 80% of the number of cookies consumed during the study

Age
From **15 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **69**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

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
Vice Chancellor for Research Affairs, Shiraz University of Medical Sciences, Zand Blvd, Shiraz, Iran

City
Shiraz

Postal code

Approval date
2015-02-02, 1393/11/13

Ethics committee reference number
CT-92-6878

Health conditions studied

1

Description of health condition studied
burn

ICD-10 code
T21

ICD-10 code description
Burn of unspecified degree of trunk

Primary outcomes

1

Description
hs-CRP(high sensetive- C Reactive Protein)

Timepoint
Before the intervention, and 21 days after intervention

Method of measurement
Elisa

2

Description
SOD(Super Oxide Dismutase)

Timepoint
Before the intervention, and 21 days after intervention

Method of measurement
Spectrophotometric

3

Description
MDA(Malondialdehyde)

Timepoint
Before the intervention, and 21 days after intervention

Method of measurement
Satoh method with thiobarbituric acid solution

Secondary outcomes

1

Description
Apparent Nitrogen balance

Timepoint
Before the intervention, and 21 days after intervention

Method of measurement
Spectrophotometric

2

Description
Total lymphocyte count

Timepoint
Before the intervention, and 21 days after intervention

Method of measurement
Spectrophotometric

3

Description
Ferritin

Timepoint
Before the intervention, and 21 days after intervention

Method of measurement

Elisa

Intervention groups

1

Description
Cookies made from 50gr Isolated Soy Protein ; 30gr Flaxseed oil ; 10gr Water ; 35gr Sugar ; 27gr fat yogurt ; 50 gr Whole milk ; 20 gr rice flour ; 20gr Chocolate or 19gr date juice or 20gr honey and 10gr nuts and 21 days is given to patients
Category
Rehabilitation

2

Description
Cookies made from 50gr Isolated Soy Protein ; 30gr Corn oil ; 10gr Water ; 35gr Sugar ; 27gr fat yogurt ; 50 gr Whole milk ; 20 gr rice flour ; 20gr Chocolate or 19gr date juice or 20gr honey and 10gr nuts and 21 days is given to patients.
Category
Rehabilitation

3

Description
Cookies made from 50gr Wheat flour; 30gr Corn oil ; 10gr Water ; 35gr Sugar ; 27gr fat yogurt ; 50 gr Whole milk ; 20 gr rice flour ; 20gr Chocolate or 19gr date juice or 20gr honey and 10gr nuts and 21 days is given to patients
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Qutb al-Din Shirazi Burn hospital
Full name of responsible person
Dr Mehdi Ayaz
Street address
Qutb al-Din Shirazi Burn hospital, Shirza
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor of Shiraz University of Medical Sciences
Full name of responsible person
Dr. Ali Poostforush
Street address
Shiraz University of Medical Sciences, Zand Blvd., Shiraz, Iran
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor of Shiraz University of Medical Sciences
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 Nutrition, Shiraz University of Medical Sciences
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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