

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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

Shiraz University of Medical Sciences

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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 Criteria : Having an allergy to soy ; consumption 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 sensitive- 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

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

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

Full name of responsible person

Abdollah Hozhabrmanesh

Position

Msc. Candidate for Nutrition

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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