

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of hydrolyzed collagen alone, or in combination with fish oil on wound healing, metabolic disorders and adipose derived peptides in patients with burn

Protocol summary

Study aim

Investigating the effect of hydrolyzed collagen alone or in combination with fish oil on wound healing, metabolic disorders, and adipose derived factors in patients with burns

Design

A randomized, double-blind, parallel design clinical trial, with two intervention groups (collagen alone and collagen plus fish oil) and a control group

Settings and conduct

In this clinical trial, patients with burn admitted to Motahari hospital will be included if they met the inclusion criteria. After obtaining a written consent, patients will be randomly divided to three groups to receive collagen alone (40 g daily), collagen plus fish oil (40 g daily plus 10 ml fish oil) and control (placebo with similar characteristics). In each group, 22 patients will receive the supplements for 4 weeks. The participants and main investigators will not be aware of the contents of the supplement and placebo. An individualized nutrition program will be provided for each patient. At the beginning, and at the end of weeks 2 and 3, a 10cc fasting blood sample will be taken. The levels of inflammatory and nutritional factors, anthropometric measurements, and clinical outcomes, including wound healing and hospitalization time, will be examined.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Burns of 20-45% of body surface area and degree 2 (deep) or 3, age 18-60 year, and the ability to oral intake of foods. Non-inclusion criteria: History of any metabolic or chronic diseases, such as diabetes and organ failures, BMI<18.5 kg/m², allergy or intolerance to protein products, pregnant women, and addicts.

Intervention groups

The protein supplement of hydrolyzed collagen will be given to patients with burn alone or with fish oil that contains essential fatty acids. The control group will

receive a placebo with the same characteristics.

Main outcome variables

Pre-albumin serum levels

General information

Reason for update

Change in the timing of the measurement of blood parameters is due to limitations and difficulties of visiting patients due to the prevalence of Covid 19. The change in the total amount of supplements is only due to the higher purity of the components, provided for this trial, and the amount of active ingredients (hydrolyzed collagen and omega-3 fatty acids) has not been changed. Adding new secondary outcomes (FGF21, NRG4, and VSS) is thanks to receiving more funding.

Acronym

-

IRCT registration information

IRCT registration number: **IRCT20090901002394N42**

Registration date: **2019-03-15, 1397/12/24**

Registration timing: **prospective**

Last update: **2021-03-06, 1399/12/16**

Update count: **1**

Registration date

2019-03-15, 1397/12/24

Registrant information

Name

Shima Jazayeri

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source**Expected recruitment start date**

2019-04-04, 1398/01/15

Expected recruitment end date

2019-12-21, 1398/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of hydrolyzed collagen alone, or in combination with fish oil on wound healing, metabolic disorders and adipose derived peptides in patients with burn

Public title

Effect of collagen and fish oil in burn

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with 20-45% total body surface area burn
Patients with burn degree of 2 (deep) or 3 Age 18-60 years
The ability of oral intake of foods

Exclusion criteria:

History of any metabolic or chronic diseases such as diabetes, cardiovascular diseases, organ failures, and etc. Body mass index < 18.5 kg/m² History of allergy or intolerance to protein products Pregnant women Drug and alcohol addicts

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

For random allocation of individuals to the three groups, the permuted block randomization method will be applied, using a computer program, and the length of blocks will be considered randomly as 3, 6 or 9.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants in this study and the main investigator who will be involved in the conduction of the project will be blind to the content of supplement and placebo. The allocation of individuals and the provision of supplement and placebo will be carried out by a person independent

of the research group.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2018-10-28, 1397/08/06

Ethics committee reference number

IR.IUMS.REC.1397.569

Health conditions studied**1****Description of health condition studied**

Burns

ICD-10 code

T21

ICD-10 code description

Burn and corrosion of trunk

2**Description of health condition studied**

Burns

ICD-10 code

T22

ICD-10 code description

Burn and corrosion of shoulder and upper limb, except wrist and hand

3**Description of health condition studied**

Burns

ICD-10 code

T24

ICD-10 code description

Burn and corrosion of lower limb, except ankle and foot

Primary outcomes

1

Description

Pre-albumin serum concentration

Timepoint

Baseline, end of weeks 2 and 3

Method of measurement

Biochemical assay

Secondary outcomes

1

Description

Body weight

Timepoint

Baseline, end of weeks 2 and 3

Method of measurement

Body scale

2

Description

Body mass index

Timepoint

Baseline, end of weeks 2 and 3

Method of measurement

Calculation based on the relevant formula

3

Description

Duration of hospital stay

Timepoint

Time of discharge

Method of measurement

Patient's records

4

Description

Wound healing

Timepoint

End of weeks 2 and 4

Method of measurement

Observation

5

Description

High-sensitivity C-reactive Protein serum concentration

Timepoint

Baseline, end of weeks 2 and 3

Method of measurement

ELISA

6

Description

Transforming growth factor beta serum concentration

Timepoint

Baseline, end of weeks 2 and 3

Method of measurement

ELISA

7

Description

Adiponectin serum concentration

Timepoint

Baseline, end of weeks 2 and 3

Method of measurement

ELISA

8

Description

Fasting blood glucose concentration

Timepoint

Baseline, end of weeks 2 and 3

Method of measurement

Biochemical assay

9

Description

Fasting insulin serum concentration

Timepoint

Baseline, end of weeks 2 and 3

Method of measurement

ELISA

10

Description

Homeostasis model assessment of insulin resistance

Timepoint

Baseline, end of weeks 2 and 3

Method of measurement

Calculation based on the relevant formula

11

Description

Daily energy intake

Timepoint

Baseline, end of weeks 2 and 3

Method of measurement

24-h dietary recall

12

Description

Daily protein intake

Timepoint

Baseline, end of weeks 2 and 3

Method of measurement

24-h dietary recall

13

Description

Fibroblast growth factor 21 serum concentration

Timepoint

Baseline, end of weeks 2 and 3

Method of measurement

ELISA

14**Description**

Neuregulin 4 serum concentration

Timepoint

Baseline, end of weeks 2 and 3

Method of measurement

ELISA

15**Description**

Vancouver Scar Scale

Timepoint

End of week 4

Method of measurement

Scoring based on a questionnaire

Intervention groups**1****Description**

Intervention group 1: Daily intake of 40 gr hydrolyzed collagen for 4 weeks

Category

Treatment - Other

2**Description**

Intervention group 2: Daily intake of 40 gr hydrolyzed collagen plus 10 ml fish oil for 4 weeks

Category

Treatment - Other

3**Description**

Control group: Placebo with same characteristics for 4 weeks

Category

Placebo

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

Motahari hospital

Full name of responsible person

Mostafa Dehmardei

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Shahid Motahari hospital, Rashid Yasemi St., Vali Asr avenue, Tehran

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

Iran University of Medical Sciences

Full name of responsible person

Dr. Seyed Alijavad Mousavi

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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

Iran University of Medical Sciences

Proportion provided by this source

60

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

2**Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

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Tehran University of Medical Sciences, Ghods St., Keshavarz Blvd, Tehran, Iran

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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

Tehran University of Medical Sciences

Proportion provided by this source

40

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

Iran University of Medical Sciences

Full name of responsible person

Shima Jazayeri

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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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