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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+98 21 8670 4805

Email address

sjazayeri@razi.tums.ac.ir

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
Street address
Shahid Motahari hospital, Rashid Yasemi St., Vali Asr avenue, Tehran
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8877 0031
Email
hospital.motahari@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Seyed AliJavad Mousavi
Street address
Iran university of medical sciences, next to Milad tower, Hemmat Highway, Tehran
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1449614535
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Email
adminsite@iums.ac.ir
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
Street address
Tehran University of Medical Sciences, Ghods St., Keshavarz Blvd, Tehran, Iran
City
Tehran
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1416643931
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office@sina.tums.ac.ir
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
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Person responsible for updating data

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Email
sjazayeri@razi.tums.ac.ir

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