

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

The effect of hydrolyzed collagen supplement alone or in combination with fish oil on gut microbiome in patients with burn

Protocol summary

Study aim

The effect of hydrolyzed collagen supplement alone or in combination with fish oil on gut microbiome in patients with burn

Design

A randomized, double- blind , placebo- controlled , parallel design trial, with two intervention groups (collagen alone and collagen + fish oil) and a control group , stratified by Permuted Block Randomization

Settings and conduct

Patient selection from Motahhari Hospital considering the inclusion and exclusion criteria, randomized allocation of patients into 3 study groups, calculating calorie and daily protein intake for all patients individually, preparation and coding of supplements and placebo as A, B, and C by a person independent of the research, examination of anthropometric measurements and obtaining stool samples.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Burns of 20-45% of body surface area and degree 2 (deep) or 3 , 18-60years old men and women , the ability to oral intake up to 48 hours after admission Exclusion Criteria: Past medical history of diabetes and other endocrine disorders, cancer, digestive disorders and malabsorption , cardiovascular and respiratory diseases, organ failure such as liver and kidney failure , infectious disease , autoimmune disease , history of allergy or intolerance to protein, pregnant or postmenopausal women , smoking , addiction , alcohol consumption, taking NSAIDs and anticoagulant medications , taking high doses of protein or omega3 fatty acid supplements within 3 months prior to study.

Intervention groups

1.Hydrolyzed collagen alone(40 gr daily+ 9 ml sunflower oil) 2.Hydrolyzed collagen in combination with fish oil(40 gr daily+ 9ml fish oil) 3.Placebo

Main outcome variables

Determination and comparison of gut Lactobacillus, Enterobacteriaceae, Bifidobacterium and firmicutes

/bacteroidetes ratio between the 3 study groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131125015536N9**

Registration date: **2019-08-01, 1398/05/10**

Registration timing: **prospective**

Last update: **2019-08-01, 1398/05/10**

Update count: **0**

Registration date

2019-08-01, 1398/05/10

Registrant information

Name

Mohammad Javad Hosseinzadeh

Name of organization / entity

School of Nutritional Sciences and Dietetics, TUMS

Country

Iran (Islamic Republic of)

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+98 21 8899 3059

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of hydrolyzed collagen supplement alone or in combination with fish oil on gut microbiome in patients with burn

Public title

Effect of collagen supplement and fish oil on gut microbiome

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Burns of 20-45% of body surface area Degree 2 (deep) or 3 18-60 years old men and women The ability to oral intake up to 48 hours after admission

Exclusion criteria:

Past medical history of diabetes and other endocrine disorders, cancer , digestive disorders and malabsorption , cardiovascular and respiratory diseases, organ failure such as liver and kidney failure , infectious diseases, and autoimmune disease History of allergy or intolerance to protein products Pregnant or postmenopausal women Smoking , addiction , alcohol consumption Taking NSAIDs and anticoagulant medications Taking high doses of protein or omega-3 fatty acid supplements within 3 months prior to study

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: **63**

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

To blind both patients and investigators , the supplements and placebo will be given in combination with foods and will be similarly coded as A, B, and C. This process is done by one of the person independent of the study in the hospital.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Tehran University of Medical Sciences

Street address

Sixth Floor , Central Organization of Tehran University of Medical Sciences , Qods St , Keshavarz Blvd .

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2019-07-08, 1398/04/17

Ethics committee reference number

IR.TUMS.VCR.REC.1398.393

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**

Determination and comparison of gut Lactobacillus

between 3 study groups
Timepoint
before and after 2 weeks of intervention
Method of measurement
Real Time PCR

2

Description
determination and comparison of gut Enterobacteriaceae
between 3 study groups
Timepoint
before and after 2 weeks of intervention
Method of measurement
Real Time PCR

3

Description
determination and comparison of gut Bifidobacterium
between 3 study groups
Timepoint
before and after 2 weeks of intervention
Method of measurement
Real Time PCR

4

Description
determination and comparison of gut Firmicutes /
Bacteroidetes ratio between 3 study groups
Timepoint
before and after 2 weeks of intervention
Method of measurement
Real Time PCR

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: hydrolyzed collagen alone (40 gr
daily + 9 ml sunflower oil)
Category
Treatment - Other

2

Description
Intervention group 2 : hydrolyzed collagen in
combination with fish oil (40 gr daily + 9 ml fish oil)
Category
Treatment - Other

3

Description
Control group: Placebo
Category

Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Motahhari Hospital
Full name of responsible person
Mostafa Dehmardei
Street address
Motahhari Hospital , Rashid Yasemi St , Valiasr Ave
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Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8877 0031
Email
hospital.motahari@yahoo.com
Web page address
<http://crtm.iums.ac.ir>

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Mohammad Ali Sahraian
Street address
Sixth floor , Central Organization of Tehran University
of Medical Sciences , Qods St , Keshavarz Blvd
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1417653761
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+98 21 8163 3685
Email
msahrai@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
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

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Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shiva Salehi

Position

M.Sc Student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Other areas of specialty/work

Nutrition

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Tehran

Postal code

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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