Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

Phone
+98 21 8899 3059

Email address
mhosseinzadeh@tums.ac.ir

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 cosumption 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
City
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
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+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

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

Street address

No:44, Hojjat-dost Alley, Naderi St. , Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1416643931

Phone

+98 21 8895 5975

Email

shivasalehi1994@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad-Javad Hosseinzadeh-Attar

Position

MD, PhD ,Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

No.44, Hojjatdoust Alley , Naderi Ave, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1416643931

Phone

+98 21 8895 5569

Email

mhosseinzadeh@tums.ac.ir

Person responsible for updating data

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

Street address

No:44, Hojjat-dost Alley, Naderi St. , Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1416643931

Phone

+98 21 8895 5975

Email

shivasalehi1994@gmail.com

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