

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Comparison effects of high-protein high-calorie supplement - based with "Collagen Hydrolysate" with soya flour supplement on wound healing in patients with 20-30 percent burns : controlled double blind clinical trial

Protocol summary

Summary

Objective: To determine the effect of supplement containing hydrolyzed collagen and compared with the same composition has on wound healing in patients with TBSA 30-20 percent .soy flour can be used as a supplement in critical condition. desine: Target population: 30 men under 70 years, 30-20TBSA burns, body mass index over 18, insensitivity to yogurt clinical trial is a double blind samples randomly divided into control and intervention.procedure: Koreerry formula of 1,000 calories, total calories in the form of supplements was evaluated. 4 snack in the intervention group: supplement containing hydrolyzed collagen protein-based bovine, yogurt, sugar and control formulations are matched based on soy flour is heated, yogurt and sugar in 4 snack will be feeding.although supplements prepare by third person .Exclusion criteria: people with underlying conditions that prohibit the consumption of high-calorie, high-protein diet, such as diabetes, kidney and liver disease, addiction, respiratory disease and those with BMI less than 18% . During the study period of 60 days (30 days in hospital and 30-day follow-up). All calories and macro nutrients include carbohydrates, protein and fat are absolutely identical in both groups.Primary outcome measure: Before feeding, 15 and 30 of the fairy albumin ; weight and Arm circumference are recorded. Photo taken ulcer. . According to the effects of collagen hydrolyze in the formulation will be evaluated on wound healing.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011015536N5**
Registration date: **2017-02-20, 1395/12/02**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-02-20, 1395/12/02

Registrant information

Name

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Name of organization / entity

School of Nutritional Sciences and Dietetics, TUMS

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Recruitment status

Recruitment complete

Funding source

vice chancellor for research,Tehran University of Medical sciences

Expected recruitment start date

2017-02-08, 1395/11/20

Expected recruitment end date

2019-01-31, 1397/11/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effects of high-protein high-calorie supplement - based with "Collagen Hydrolysate" with soya flour supplement on wound healing in patients with 20-30 percent burns : controlled double blind clinical trial

Public title

Effects of high-protein high-calorie supplement -content
"Collagen Hydrolysate" on wound healing in burns

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients (men); less than 70 years;
body mass index higher than 18; TBSA 30-20 burns
Exclusion criteria: patients with underlying conditions
that prohibit the consumption of high-calorie- high-
protein diet such as: diabetes; kidney disease; liver
disorders; addiction; respiratory disease; those with BMI
less than 18 and people who are allergic to yogurt

Age

From **20 years** old to **69 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

In this study, using a table of random numbers of groups
are divided into two groups. Intervention and control.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical
science

Street address

6th floor Ghods street Keshavarz Bolivar

City

Tehran

Postal code

-

Approval date

2017-01-21, 1395/11/02

Ethics committee reference number

IR.TUMS.VCR.REC.1395.848

Health conditions studied

1

Description of health condition studied

Burn

ICD-10 code

T21

ICD-10 code description

Burn and corrosion of trunk

Primary outcomes

1

Description

pre Albomin

Timepoint

befor intervention: 15days after intervention and 30days
after intervention

Method of measurement

Blood test in torbidometri method

2

Description

photography

Timepoint

befor intervention: 15days after intervention and 30days
after intervention

Method of measurement

SONY camera measuring the size of wound in cm

3

Description

weight

Timepoint

befor intervention: 15days after intervention and 30days
after intervention

Method of measurement

scale

4

Description

Length of hospital stay

Timepoint

befor intervention: 15days after intervention and 30days
after intervention

Method of measurement

Medical history folder

Secondary outcomes

1

Description

Arm circumference

Timepoint

befor intervention day 15 and 30

Method of measurement

meter

Intervention groups

1

Description

Intervention group:supplement include: yogurt (3.5% fat), Gelatin" Amootiya" and sugar. with calories and fat, protein,Fat and carbohydrate quite similar to the placebo group for 30 days and 4 snack per day would be given to patients and It prepare by third person.

Category

Placebo

2

Description

Control group: placebo include: yogurt(3.5% fat), heated soy flour and sugar. with calories and fat, protein and carbohydrate quite similar to the intervention group for 30 days and 4 snack per day would be given to patients and It prepare by third person.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahari Burn hospital

Full name of responsible person

Dr RezaVaghardoost

Street address

Yasemi street Zafar station Valiasr Street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for ResearchTehran University of Medical sciences

Full name of responsible person

Deputy of research and technology medical University Tehran

Street address

Room No 605 sixth flooor Ghods stirt Keahvarz Bolivar

City

TEHRAN

Grant name

-

Grant code / Reference number

-

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for ResearchTehran 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

Tehran University of Medical Sciences Department of Nutrition and Dietetic

Full name of responsible person

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Position

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Person responsible for updating data

Contact

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Medicin Tehran University

Full name of responsible person

Katayoun Bagheri miyab

Position

Master student of Nutrition indisaster

Other areas of specialty/work**Street address**

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Web page address

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