Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of oral Flaxseed oil And Olive oil on wound size and Inflammation markers in burn patients

Protocol summary

Study aim

Determining the effect of oral Flaxseed oil And Olive oil on wound size and Inflammation markers in burn patients

Design

In this placebo-controlled, double-blind, parallel-group, randomized clinical trial, 112 patients with 20-50% burns will be recruited from the Institute of Burn Research of The Velayyat hospital in Rasht, Iran. By using blocks randomization, participants will be assigned to 4 equal groups.

Settings and conduct

This research will work on wound size in burn patients in Velayat center. Two vegetable oils are consumed in the diet of patients and their effects on inflammation and wound size are measured. Measurement of wound size will be done by taking pictures of wounds, examining the appearance of ulcers. hs-CRP, ferritin, albumin, are performed by blood analysis. The study is double blind, in which the olive oil without odor and flaxseed oil is stored in dark glasses with no name. Not patients, nor nutritionists know the type of oil.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age of 15–65; Body mass index of 18–30 kg/m2; Hospitalization for more than 24-hours; Admitting within 24 - 48h post-burn; Willingness to participate; Able to feed the mouth. Exclusion Criteria: Infected wounds; Cases of underlying diseases; Allergy to Flaxseed or Olive; History of taking omega-3, omega-6 in the previous month; pregnant and lactating women; Smoking.

Intervention groups

The patients will randomly be assigned to 4 groups consisting of 1)28 Patients in the olive oil group, 2)28 in the flaxseed oil group, 3)28 in the control group and 4)28 in the combined group. Patients in group 1 receive 30cc of olive oil daily, group 2 receive 30cc flaxseed oil and group 4 receive 15 cc olive oil plus 15cc flaxseed oil in their salad in the lunch or dinner.The control group will eat salads without oil in a meal.

Main outcome variables

Wound Size, hs-CRP, Ferritin, Albumin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080901001174N11**
Registration date: **2018-03-26, 1397/01/06**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-26, 1397/01/06**
Update count: **0**

Registration date

2018-03-26, 1397/01/06

Registrant information

Name

Atefeh Ghanbari

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13780509

Email address

at_ghanbari@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-06, 1396/12/15

Expected recruitment end date

2018-07-06, 1397/04/15

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of oral Flaxseed oil And Olive oil on wound size and Inflammation markers in burn patients

Public title
Effect of Edible herbal oils on wound size
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age of 15–65 years Body mass index (BMI) of 18–30 kg/m2 Hospitalization for more than 24 hours Admittion within 24 - 48 h post-burn Willingness to participate Able to feed through the mouth
Exclusion criteria:
Infected burn wounds Cases of chronic and underlying diseases Allergy to Flaxseed oil And Olive oil The history of taking omega-3 and omega-6 in the previous week or month pregnant and lactating women Smoking
Age
From **15 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **112**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients who referred to this center with% 20-50% burns are randomly divided into four groups using randomized blocks. Intervention variables include age and sex, and patients under the transplanted skin that can be controlled and categorized in a random blocked stratified method.
Blinding (investigator's opinion)
Double blinded
Blinding description
Odorless olive oil and flaxseed oil in dark glass without the name (nickname) are prepared and maintained by the Investigator. Not patients, nor nutritionists, know the type of oil. Vegetable oil is intended for use by a Nutritionist who does not know about the contents of the glass in the patient's salad, or if the patient is discharged, dark glass bottle contains unnamed oil, would be Available to the patient. It should be noted that both oils are golden yellow. Flaxseed oil has very little odor for 7 days and can not be distinguished from odorless olive oil.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical committee, Guilan University of Medical Sciences
Street address
Guilan University of Medical Sciences, Namjoo Street
City
Rasht
Province
Guilan
Postal code
4193833697
Approval date
2018-02-26, 1396/12/07
Ethics committee reference number
IR.GUMS.REC.1395.501

Health conditions studied

1

Description of health condition studied
Wound size
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Wound size
Timepoint
Before intervention and 2, 9, 15, and 22 days after the intervention
Method of measurement
Getting photo from burn injury and measure the length and width of the wound to measure the area of the wound; Canon's camera model and a standard ruler will be used for this purpose. The area of the wound is measured by the AutoCAD software. Changing the area and the appearance of the wound will be considered as wound healing. When the wound appearance become pink and transparent with the non-secreting epithelium the wound will be considered as healed wound.

Secondary outcomes

1

Description
hs-CRP
Timepoint
At the beginning and at the end of the study
Method of measurement
Blood test

2

Description
Ferritin
Timepoint
At the beginning and at the end of the study
Method of measurement
Blood test

3

Description
Albumin
Timepoint
At the beginning and at the end of the study
Method of measurement
Blood test

Intervention groups

1

Description
Intervention group 1: 28 patients are in group A and receive 30 cc of olive oil mixed with salad, daily, in a meal for 21 consecutive days.Extra virgin olive oil from olives was prepared by household oiling machines. Analysis of fatty acid profiles and antioxidants and its polyphenols by GC / MS machine in Raymi chemical specialty lab using gas chromatography and spectroscopy at www.afshinrahimilab.com will be done.
Category
Treatment - Other

2

Description
Intervention group 2: 28 patients are in group B and receive 30 cc of Flaxseed oil mixed with salad, daily, in a meal for 21 consecutive days. Extract of flaxseed oil from flaxseed was prepared by household oiling machines. Analysis of fatty acid profiles and antioxidants and its polyphenols by GC / MS machine in Raymi chemical specialty lab using gas chromatography and spectroscopy at www.afshinrahimilab.com will be done. also, titration of peroxide endometritis on flaxseed oil will be done and will be expressed in milligrams of active oxygen in a kilogram of oil.
Category
Treatment - Other

3

Description
Intervention group 3: 28 patients are in group D and receive 15 ccs of Flaxseed oil mixed with 15 ccs of olive oil salad, daily, in a meal for 21 consecutive days.
Category
Treatment - Other

4

Description
Control group: 28 patients are in group C and they will eat the salad without oil In a meal, for 21 consecutive days. Patients'salads are based on the diet adjusted by the nutritionist to suit each patient. All four groups will receive routine treatment, which includes vitamin E and vitamin A on a daily basis.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Velayyat hospital
Full name of responsible person
Atefeh Ghanbari
Street address
Faculty of Nursing and Midwifery, Daneshjo street, Shahid Beheshti Highway, Rasht
City
Rasht
Province
Guilan
Postal code
3984141469
Phone
+98 13 3355 5058
Fax
+98 13 3355 0097
Email
at_ghanbari@gums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Dr. Shadman Nemati
Street address
Deputy of research Building, Shahid Siadati Ave ,Namjoo Ave,Rasht
City
Rasht
Province
Guilan
Postal code
4146939114
Phone

+98 13 3333 6394

Email

research@gums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Atefeh Ghanbari

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Faculty of Nursing and Midwifery, Daneshjo street,Shahid Beheshti Highway, Rasht

City

Rasht

Province

Guilan

Postal code

3984141469

Phone

+98 33555056

Fax

+98 13 3355 0097

Email

at_ghanbari@gums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Atefeh Ghanbari

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Faculty of Nursing and Midwifery, Daneshjo street,Shahid Beheshti Highway, Rasht

City

Rasht

Province

Guilan

Postal code

3984141469

Phone

+98 33555056

Fax

+98 13 3355 0097

Email

at_ghanbari@gums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Atefeh Ghanbari

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Faculty of Nursing and Midwifery, Daneshjo street,Shahid Beheshti Highway, Rasht

City

Rasht

Province

Guilan

Postal code

3984141469

Phone

+98 13 3355 5056

Fax

+98 13 3355 0097

Email

at_ghanbari@gums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Main and total Data

When the data will become available and for how long

starting in 2018

To whom data/document is available

Universities and scientific institutions

Under which criteria data/document could be used

If they cite the article

From where data/document is obtainable

executor of proposal

What processes are involved for a request to access data/document

Contact with proposal executor and making ethical agreement

Comments