

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### Evaluation of Local Effect of Cuttlebone Lipogel on Sub-Cutaneous Fat Accumulation in women; A Randomized, Placebo-Controlled, Double-Blinded Study

#### Protocol summary

##### Study aim

Local Effect of Cuttlebone Lipogel on Sub-Cutaneous Fat Accumulation in women

##### Design

The study group consisted of 30 women. A placebo controlled clinical trial, with parallel groups, double-blind, randomized. the first phase is on 30 female patients.

Excel software rand function was used for randomization.

##### Settings and conduct

In human study, questionnaire method and is used. Also, this study is performed as a randomized, double-blind placebo controlled. therefore: 30 patients were randomly selected by a physician and divided into 2 groups of 15, one group will receive lipogel containing sea floor extract and the other group will receive a placebo.patients and the researcher are blinded. The duration of the study is 12 weeks. This study was conducted at Mazandaran University of Medical Sciences.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: includes obesity around the abdomen and excess fat on the sides and abdomen more than 80 cm and BMI more than 25. Exclusion criteria: People under 18 and over 50, pregnant women, people with systemic diseases leading to obesity, people taking certain obesity-causing drugs and people who are allergic to plant and seafood products.

##### Intervention groups

The 30 patients in the study were divided into 2 groups of 15, one of which would receive lipogels containing the extract (as the test group) and the other group would receive a placebo.

##### Main outcome variables

Waist size ,Waist-Hip ratio(WHR), blood serum lipid profiles including low and high density lipoproteins(LDL& HDL), cholesterol, Triglyceride.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130911014630N10**

Registration date: **2022-05-13, 1401/02/23**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-05-13, 1401/02/23**

Update count: **0**

##### Registration date

2022-05-13, 1401/02/23

##### Registrant information

##### Name

Mohammad Azadbakht

##### Name of organization / entity

Mazandaran University of Medical Scinecee

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3354 3728

##### Email address

mazadbakht@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-05-21, 1398/02/31

##### Expected recruitment end date

2022-05-23, 1401/03/02

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Evaluation of Local Effect of Cuttlebone Lipogel on Sub-Cutaneous Fat Accumulation in women; A Randomized, Placebo-Controlled, Double-Blinded Study

### Public title

Evaluation of Local Effect of Cuttlebone Lipogel on Sub-Cutaneous Fat Accumulation

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

obese women referring to a specialist Age range 18 to 50 years patient has a disorder of subcutaneous fat accumulation patient has a personal dissatisfaction with the use of the product.

#### Exclusion criteria:

People under 18 and over 50 pregnant women people with systemic diseases leading to obesity people taking certain obesity-causing drugs people who are allergic to plant and seafood products

### Age

From **18 years** old to **50 years** old

### Gender

Female

### Phase

N/A

### Groups that have been masked

- Participant
- Data analyser

### Sample size

Target sample size: **30**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Excel software was used for randomization. Using the Rand function in Excel software, random numbers are obtained and using these numbers, each person in the study is placed in drug or placebo group.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

In this Study, patients and Data Analyzer have no information about the product that it is drug or placebo. the products have given pre - determined cods and randomly assigned to the patients.

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Mazandaran University of Medical Sciences

##### Street address

Prophet Mohammad Medical Sciences Complex.Farahabad Street

##### City

Sari

##### Province

Mazandaran

##### Postal code

48188-69378

#### Approval date

2019-06-17, 1398/03/27

#### Ethics committee reference number

IR.MAZUMS.REC.1398.571

## Health conditions studied

### 1

#### Description of health condition studied

Sub-Cutaneous Fat Accumulation

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Localized obesity or waist size

#### Timepoint

at baseline and after 12 week

#### Method of measurement

Tape meters

### 2

#### Description

Waist-Hip Ratio

#### Timepoint

at baseline and after 12 week

#### Method of measurement

Tape meters

### 3

#### Description

blood serum lipid profile including Triglycerides, cholesterol and Low and high density lipoproteins.

#### Timepoint

at baseline and after 12 week

#### Method of measurement

Blood test

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: 15 individual received Cuttlebone Lipogel. At this stage, based on the recommended amounts of traditional medicine and taking into account the non-toxicity, the amount of Cuttlebone consumption per 100 grams of the gel base is 10 grams and the amount of lipogel consumption three times a day is about 5 grams for an area of 250cm<sup>2</sup> (25 × 10 cm) from the person's abdomen will be considered. Duration of the intervention is 12 weeks.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: 15 patients were randomly selected and received placebo for 12 weeks, 3 times a day. 5 grams of the gel applies on 250 cm<sup>2</sup> of abdominal area. The placebo contains all the ingredients of the main medicine, but the active ingredient of the sea floor has been removed

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Tuba Medical Center - Mazandaran University of Medical Science

##### Full name of responsible person

Dr. Mohammad Azadbakht - Dr.Ghasem Rahmatpour Rokni

##### Street address

Tuba Medical Center, Farah Abad Square, Khazar Boulevard, Sari, Mazandaran, Iran

##### City

Sari

##### Province

Mazandaran

##### Postal code

48188-69378

##### Phone

+98 911 151 3032

##### Email

Azadbakhtm@hotmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Faculty of Pharmacy

##### Full name of responsible person

Dr Mohammad Azadbakht

##### Street address

Farah abad street

##### City

Sari

##### Province

Mazandaran

##### Postal code

4847191971

##### Phone

+98 911 151 3032

##### Email

Azadbakhtm@hotmail.com

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Vice chancellor for research, Faculty of Pharmacy

##### 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

Mazandaran University of Medical Sciences

##### Full name of responsible person

Mohammad Azadbakht

##### Position

Professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Medical Pharmacy

##### Street address

18 KM Kazarabad Road, The Campus of Mazandaran University of Medical Sciences and health services

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##### Province

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##### Fax

##### Email

mazadbakht@mazums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Fatemeh Akbari

**Position**

Student of Natural Medicinal and Marine Compounds College - Sari

**Latest degree**

Master

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Payambar Azam Medicinal Complex-Pharmacy College - Sari

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**Web page address**

## 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**

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**

Yes - There is 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

**Title and more details about the data/document**

Results from clinical trials

**When the data will become available and for how long**

1400/12/10

**To whom data/document is available**

Researchers working in academic institutions

**Under which criteria data/document could be used**

Use of results is allowed only with the mention of the source and In order to expand the study

**From where data/document is obtainable**

Fatemeh Akbari, 09128518809,

f\_akbari1987@yahoo.com

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

At the request of the researcher, once the medicinal product has been registered, the documents will be sent to the applicant immediately.

**Comments**

This plan will be at the disposal of the author for further studies until reaching the pharmaceutical product.

## Person responsible for updating data

### Contact

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Fatemeh Akbari

**Position**

. Student of Natural Medicinal and Marine Compounds College -Sari

**Latest degree**

Master

**Other areas of specialty/work**

Medical Pharmacy

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