

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Iranian traditional sorbet on Xerostomy, body mass index and food intake on elderly people in Thamenolaemeh elderly home- Shahroud 1394 HS

Protocol summary

Summary

This pre-post intervention study will be conducted on elderly people living in Thamenolaemeh elderly home with Xerostomy. The purpose of this study is to evaluate the effect of Iranian traditional sorbet on Xerostomy, food intake and body mass index among residence in Thamenolaemeh elderly home. Subjects of the study should have Mini Mental Status Exam score higher than 12 and are able to eat orally independently or with help. Elderly residence who are on Nasogastric tube feeding are excluded from the study. The intervention will be drinking Iranian traditional sorbet two times a day, one hour before lunch and dinner. The study will last for six consecutive weeks and glacial sorbet will be served for elderly people. Subjects will be evaluated for dry mouth, food intake and body mass index after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015052116285N2**

Registration date: **2015-06-08, 1394/03/18**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-06-08, 1394/03/18

Registrant information

Name

Ali Dadgari

Name of organization / entity

Shahroud University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 23 3239 5054

Email address

dadgari@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahroud University of Medical Sciences

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Iranian traditional sorbet on Xerostomy, body mass index and food intake on elderly people in Thamenolaemeh elderly home- Shahroud 1394 HS

Public title

Effect of Iranian traditional sorbet on Xerostomy, body mass index and food intake on elderly people

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: Being 60 years old and above; hospitalized in elderly home Exclusion Criteria: Mini mental status score 12 or less; feeding way other than oral

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahroud University of Medical Sciences

Street address

7 Tir Sq

City

Shahroud

Postal code

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

IR.SHMU.REC. 1394.33

Health conditions studied

1

Description of health condition studied

Dry Mouth

ICD-10 code

K11.7

ICD-10 code description

Disturbances of salivary secretion

Primary outcomes

1

Description

Food Intake

Timepoint

Before and one week after intervention

Method of measurement

Food intake questionnaire

2

Description

Body Mass Index

Timepoint

Before and one week after intervention

Method of measurement

BMI Scale

3

Description

Xerostomy reduction

Timepoint

Before and one week after intervention

Method of measurement

Xerostomy Scale

Secondary outcomes

empty

Intervention groups

1

Description

In this study, 50ml Iranian glacial sorbet composed of natural fruit juice free of sugar and other synthetic products will be made by sorbet making machine of Danob Company and will be served for 6 consecutive weeks two times a day, one hour before lunch and dinner. In this clinical trial there is no control group and pre-post comparison will be done

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Thamenolaemeh elderly home

Full name of responsible person

Ali Dadgari

Street address

City

Shahroud

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Dr Mohammad Mirrezaei

Street address

Shahroud University of Medical Sciences

City

Shahroud

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahroud 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

Shahroud University of Medical Sciences

Full name of responsible person

Ali Dadgari

Position

PhD Candidate

Other areas of specialty/work

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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