

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Identification and modification of rheological properties of beverages, desserts, and food in patients with esophagus cancer dysphagia and assessment of the rheological modification on improving nutritional indices and quality of life in these patients

Protocol summary

Summary

The purpose of present study is the modification of rheological properties of beverages, desserts, and foods for dysphagic patients. 40 patients of Atrak clinic (who are in the second phase of esophagus cancer) are divided into two groups. First group are using their conventional diet and the second group uses modified foodstuffs. The effect of the rheological modification on improving nutritional status and the quality of life in these patients will be assessed in an open-label clinical trial, after 3 month.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012072410380N1**

Registration date: **2012-12-18, 1391/09/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-12-18, 1391/09/28

Registrant information

Name

Azizollaah Zargaraan

Name of organization / entity

National Nutrition and Food Technology Research Institute

Country

Iran (Islamic Republic of)

Phone

+98 21 4467 3175

Email address

aziz.zargaran@gmail.com

Recruitment status

Recruitment complete

Funding source

National Nutrition and Food Technology Research Institute

Expected recruitment start date

2012-09-09, 1391/06/19

Expected recruitment end date

2012-11-09, 1391/08/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Identification and modification of rheological properties of beverages, desserts, and food in patients with esophagus cancer dysphagia and assessment of the rheological modification on improving nutritional indices and quality of life in these patients

Public title

Identification of rheological properties of desirable foodstuffs for Iranian dysphagic patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: patients who have esophageal dysphagia (from esophageous cancer); patients are in the second phase of esophageous cancer (starting chemotherapy). Exclusion criteria: the tendency of samples to exclude from study.

Age

No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National Nutrition and Food Technology Research
Institute

Street address

No. 7, West Arghavan St., Farahzadi Blvd., Shahrake
Qods (west), Tehran, Iran. Zip Code: 1981619573,
P.O.Box: 19395-4741

City

Tehran

Postal code

1981619573

Approval date

2012-12-02, 1391/09/12

Ethics committee reference number

047474

Health conditions studied

1

Description of health condition studied

dysphagia

ICD-10 code

R13

ICD-10 code description

Difficulty in swallowing

Primary outcomes

1

Description

percentage of body weight loss(%BWL)

Timepoint

at the start and 3 months after intervention

Method of measurement

scale

2

Description

triceps(TSF) and subscapular skin fold(SSF)

Timepoint

at the start and 3 months after intervention

Method of measurement

caliper

3

Description

mid arm circumference(MAC)

Timepoint

at the start and 3 months after intervention

Method of measurement

Tape Measure

4

Description

arm muscle circumference(AMC)

Timepoint

at the start and 3 months after intervention

Method of measurement

Tape Measure

5

Description

Serum Total Proteins

Timepoint

at the start and 3 months after intervention

Method of measurement

Electrophoresis

6

Description

Serum C-reactive protein

Timepoint

at the start and 3 months after intervention

Method of measurement

Elisa

7

Description

Albumin

Timepoint

at the start and 3 months after intervention

Method of measurement

Elisa

8

Description

Transferrin

Timepoint

at the start and 3 months after intervention

Method of measurement

Electrophoresis

9

Description

Pre-Albumin

Timepoint

at the start and 3 months after intervention

Method of measurement

Electrophoresis

10

Description

Hematocrit

Timepoint

at the start and 3 months after intervention

Method of measurement

coagulation

11

Description

Total Lymphocyte

Timepoint

at the start and 3 months after intervention

Method of measurement

microscopic

12

Description

Prognostic Nutritional Index (PNI)

Timepoint

at the start and 3 months after intervention

Method of measurement

$158 - 16.6(\text{Alb}) - 0.78(\text{Ts}) - 0.20(\text{Trn}) - 5.8(\text{DH})$

Secondary outcomes

1

Description

appetite

Timepoint

at the start and 3 month after intervention

Method of measurement

questionnaire

2

Description

Energy intake

Timepoint

at the start and 3 month after intervention

Method of measurement

questionnaire

3

Description

Micronutrient intake

Timepoint

at the start and 3 month after intervention

Method of measurement

questionnaire

4

Description

macronutrient intake

Timepoint

at the start and 3 month after intervention

Method of measurement

questionnaire

5

Description

Quality of life

Timepoint

at the start and 3 month after intervention

Method of measurement

questionnaire

6

Description

enjoyment from foodstuffs

Timepoint

3 month after intervention

Method of measurement

vas

Intervention groups

1

Description

Intervention group uses the rheologically modified foodstuffs, along with common diet (one product from each item)

Category

Treatment - Other

2

Description

control group: there isn't any intervention they use their conventional diet

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Atrak Clinic

Full name of responsible person

Dr. Reza Malekzadeh

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No 1, Sayyad-e-shirazi highway, Gonbad-e-kavous

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

National Nutrition and Food Research Institute

Full name of responsible person

Dr. Hajifaraji

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No. 7, West Arghavan St., Farahzadi Blvd., Shahrake
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City

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Grant name

10533

Grant code / Reference number

474

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

Yes

Title of funding source

National Nutrition and Food Research Institute

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

National Nutrition and Food Technology Research
Institute

Full name of responsible person

Azizollah Zargaraan

Position

Ph.d Student

Other areas of specialty/work

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Other areas of specialty/work

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Web page address	<i>empty</i>
Sharing plan	Informed Consent Form
	<i>empty</i>
Deidentified Individual Participant Data Set (IPD)	Clinical Study Report
<i>empty</i>	<i>empty</i>
Study Protocol	Analytic Code
<i>empty</i>	<i>empty</i>
Statistical Analysis Plan	Data Dictionary
	<i>empty</i>