

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Efficacy of medical nutrition therapy vs. general dietary advices on nutritional status of esophageal cancer patients receiving concurrent neo-adjuvant chemo-radiation

Protocol summary

Summary

This is a randomized controlled trial which is planned to perform in Reza radiation Oncology Centre (RROC), Mashhad. Pathologically proven esophageal cancer patients who meets the inclusion/exclusion criteria referred to RROC will be enrolled. All patients will fill the consent. For each patient a random number in a closed pocket will be allocated and they will be divided in two groups of intervention and control by random allocation using pocket method. Intervention group will receive specific medical nutrition therapy as their individual needs including dietary advices, oral nutrition support or enteral nutrition or parenteral nutrition. Control group will receive routine care and general dietary advices. The information will be gotten 3 times including before chemo-radiation, after chemo-radiation and 4 to 6 weeks after chemo-radiation, before surgery, which include demographic data, nutritional status of patients including Patient Generated-Subjective Global Assessment tool (PG-SGA), 3 days 24 hour recall, anthropometric measurements, body composition by Bio-electric Impedance Analysis, clinical symptoms associated with digestion and blood and biochemical factors (including total lymphocyte count, total protein, albumin, hs-CRP, urea, creatinine, SGOT, SGPT, cholesterol, triglyceride, HDL, LDL, and pro-inflammatory and anti-inflammatory cytokines. Other contributing factors of nutritional status of patients will also be assessed including socio-economic status, disease related factors, drug history, quality of life, psychological status. Three months after intervention, survival of patients will be asked.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016112931161N1**

Registration date: **2017-06-25, 1396/04/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-25, 1396/04/04

Registrant information

Name

Sara Movahed

Name of organization / entity

Mashhad Uneversity of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3800 2417

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movahheds921@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Mashhad University of Medical Sciences Cancer Research Center of Mashhad University of Medical Sciences Reza Radiation Oncology Center

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of medical nutrition therapy vs. general dietary advices on nutritional status of esophageal cancer patients receiving concurrent neo-adjuvant chemo-radiation

Public title

Efficacy of nutrition therapy on treating esophageal cancer patients

Purpose

Treatment

Inclusion/Exclusion criteria

All patients 18 years old and more referred to Reza Radiation Oncology Center which esophageal cancer is proven pathologically and agree to participate and fill the consent, will be enrolled. Patients who are end stage (who have metastasis, trachea, mediastinal main vessels or vertebra involvement), receive palliative care, history of other cancers, esophageal surgery, concurrent disabling diseases such as CHF, CRF, COPD, Liver failure, AIDS or active rheumatic diseases and also subjects who cannot fill the questionnaires will not be enrolled. patients who do not desire to continue cooperation in study will be excluded.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

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

Ethics committee of Mashhad University of Medical Sciences

Street address

Daneshgah St., Qoreishi Building

City

mashhad

Postal code

9138813944

Approval date

2016-08-17, 1395/05/27

Ethics committee reference number

IR.MUMS.REC.1395.111

Health conditions studied

1

Description of health condition studied

esophagus cancer

ICD-10 code

C15

ICD-10 code description

Malignant neoplasm of esophagus

Primary outcomes

1

Description

nutritional Status

Timepoint

before radiotherapy, after radiotherapy, 4 to 6 weeks after radiotherapy

Method of measurement

PG-SGA tool (questionnaire)

Secondary outcomes

1

Description

patient weight

Timepoint

Before radiotherapy, after radiotherapy, 4 to 6 weeks after radiotherapy

Method of measurement

weight scale

Intervention groups

1

Description

Intervention: Medical nutrition therapy including dietary advises, oral nutrition support or enteral nutrition or parenteral nutrition according to patients' nutritional status and signs and symptoms related to ingestion ability.

Category

Treatment - Other

2

Description

Control group: General dietary advice

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Reza Radiation Oncology Center

Full name of responsible person

Dr. Fatemeh Varshoei Tabrizi

Street address

Misaq 19, Misaq highway, Vakil abad Blvd

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Daneshgah St., Qoreishi Building

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Mashhad

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 of Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

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Position

MD. PhD. candidate of nutrition sciences

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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