

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Evaluation the efficacy of polyamine-deprived dietary regimen on Angiogenic growth factors and Tumor markers in patients with Lung cancer

Protocol summary

Summary

Main goal: Evaluation the efficacy of polyamine-deprived dietary regimen on Angiogenic growth factors and Tumor markers in patients with Lung cancer, Inclusion Criteria: age between 30 to 70; healthy function of liver and kidney; lung cancer diagnosis Exclusion Criteria: Chemotherapy; Food supplement or other dietary regimen; diabetes patients. Patients with lung cancer between 30 to 70 which referred to Shafa Hospital under supervision of Oncologist will recruit in this study. Sample size in each group will be 30. All of them before chemotherapy divided in two groups and then under the supervision of dietitian will be under specific regimen with low level of polyamine and for inhibition of intestinal production of polyamine give Neomycin. 5 cc blood from all participant will obtain and blood keep in -30 C until analysis, for analyzing following parameters : Hepatic Growth Factor, Eidermal Growth Factor Receptor, Matrix MetalloProteinase 1, TIMP Metalloproteinase Inhibitor 1, Plasminogen Activator Inhibitor 1, urokinase (uPA)-mediated plasminogen activation, Vascular cell adhesion protein 1, Intercellular Adhesion Molecule 1, and tumor markers including Squamous Cell Carcinoma, Carcinoembryonic antigen Cyfra-21 and also Interleukin -10 Interleukin 2

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016020626390N1**

Registration date: **2016-06-18, 1395/03/29**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-06-18, 1395/03/29

Registrant information

Name

Ehsan Ghaedi

Name of organization / entity

Ahwaz Jundishapoor ,University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Ahwaz Jondishapoor University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the efficacy of polyamine-deprived dietary regimen on Angiogenic growth factors and Tumor markers in patients with Lung cancer

Public title

Evaluation the efficacy of polyamine-deprived dietary regimen Lung cancer

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: age between 30 to 70; healthy function of liver and kidney; lung cancer diagnosis
Exclusion Criteria: Chemotherapy; Food supplement or other dietary regimen; diabetes patients

Age

From **16 years** old to **88 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahwaz jondishapoor uneversity of medical sciences

Street address

a

City

ahwaz

Postal code

.

Approval date

2016-01-23, 1394/11/03

Ethics committee reference number

IR.AJUMS.REC.1394.590

Health conditions studied

1

Description of health condition studied

lung cancer

ICD-10 code

C34

ICD-10 code description

Malignant neoplasm of bronchus and lung

Primary outcomes

1

Description

Hepatic Growth Factor

Timepoint

befor and after

Method of measurement

Labaratory Kits,

2

Description

Eidermal Growth Factor Receptor

Timepoint

befor and after

Method of measurement

Labaratory Kits,

3

Description

Matrix MetalloProteinase 2

Timepoint

befor and after

Method of measurement

Labaratory Kits,

4

Description

TIMP Metallopeptidase Inhibitor 1

Timepoint

befor and after

Method of measurement

Labaratory Kits,

5

Description

Plasminogen Activator Inhibitor 1

Timepoint

befor and after

Method of measurement

Labaratory Kits,

6

Description

urokinase (uPA)-mediated plasminogen activation

Timepoint

befor and after

Method of measurement

Labaratory Kits,

7

Description

Vascular cell adhesion protein 1

Timepoint

befor and after

Method of measurement

Labaratory Kits,

8

Description

Intercellular Adhesion Molecule 1

Timepoint

befor and after

Method of measurement

Labaratory Kits,

9

Description

Squamous Cell Carcinoma

Timepoint

befor and after

Method of measurement

Labaratory Kits,

10

Description

Carcinoembryonic antigen

Timepoint

befor and after

Method of measurement

Labaratory Kits,

11

Description

Cyfra-21

Timepoint

befor and after

Method of measurement

Labaratory Kits,

12

Description

Interleukin -10

Timepoint

befor and after

Method of measurement

Labaratory Kits,

13

Description

Interleukin 2

Timepoint

befor and after

Method of measurement

Labaratory Kits,

Secondary outcomes

1

Description

weight

Timepoint

befor and after

Method of measurement

kg

Intervention groups

1

Description

Patients will experience poly amine restricted diet under supervision of of dietition for 6 month intervention group

Category

Treatment - Other

2

Description

In control group by the Adjusted Ideal Body weight will be under supervision of Dietition,

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

ShAfa Hospital

Full name of responsible person

Dr. Ahmadzade, Oncologist

Street address

Shafa Hospital, Farvardin Street, Golestan Bolvard,
Ahwaz

City

Ahwaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahwaz Jundishapur University of Medical Science

Full name of responsible person

Nader Saaki

Street address

Ahwaz

City

Ahwaz

Grant name

.

Grant code / Reference number

.

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

Yes

Title of funding source

Ahwaz Jundishapur University of Medical Science

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
Ahwaz Jundishapoor University of Medical Science
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Person responsible for scientific inquiries

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<http://hshafa.ajums.ac.ir/>

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