Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 betwwen 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 befor chemotherapy devided in two groups and then under the supervision of dietition will be under specefic 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 Metallopeptidase 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-21and 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
+98 61 3374 3285
Email address
ghaedi.e@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source
Ahwaz Jondishapoor University of Medical Sceinces

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

Full name of responsible person

Ahmad Ahmadzadeh

Position

Oncologist

Other areas of specialty/work

Street address

Shafa Hospital, Ahwaz

City

Ahwaz

Postal code

Phone

+98 61 3374 3285

Fax

Email

m_pedram@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hemoglubinopathy Center

Full name of responsible person

Ehsan Ghaedi

Position

Nutritionist

Other areas of specialty/work

Street address

Hemoglobinopathy Center, Ahwaz

City

Ahwaz

Postal code

Phone

+98 61 3374 3285

Fax

Email

en7cyrus@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Haemoglubinopathy Center

Full name of responsible person

Ehsan Ghaedi

Position

Nutritionist

Other areas of specialty/work

Street address

Haemoglubinopathy Centerو Shafa Hospital, Ahwaz

City

Ahwaz

Postal code

6135733119

Phone

+98 61 3374 3285

Fax

+98 61 3374 3289

Email

Web page address

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