Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of Pentoxifylline treatment on quality of life and change in arm circumference compared to placebo in patients with cancer cachexia: A double-blind, randomized, placebo-controlled trial

Protocol summary

Summary

This interventional study was design to assess the effect of Pentoxifylline treatment on quality of life and change in arm circumference compared to placebo in patients with cancer cachexia. 70 patients with advanced malignancy who have lost more than 5% of their ideal or body weight in the previous 2 months, will be enrolled. Patients with histologic or cytologic proof of cancer, and incurable malignancy with a life expectancy ≥ 4 months are eligible if they don't have edema or ascites and adrenal corticosteroids treatment. Eligible patients will be randomly divided into two 35-member groups of intervention and control groups. Intervention group used Pentoxifylline (400 mg) three times a day, and controls will receive placebo three times a day. Treatment will be continued for a period of 2 months. Also patients will be unaware of the treatment allocation and will follow monthly by a doctor who is blinded to the study groups. Age, sex, weight change, change in arm circumference and quality of life are variables to be observed in this study. Change in arm circumference and quality of life as main outcome variables will be assessing at baseline, week-4 and week-8.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013081410297N2**
Registration date: **2013-11-23, 1392/09/02**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-11-23, 1392/09/02

Registrant information

Name

Leili Allahbakhshian

Name of organization / entity

Isfahan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2011-10-15, 1390/07/23

Expected recruitment end date

2012-06-15, 1391/03/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Pentoxifylline treatment on quality of life and change in arm circumference compared to placebo in patients with cancer cachexia: A double-blind, randomized, placebo-controlled trial

Public title

Effect of Pentoxifylline treatment on quality of life and change in arm circumference compared to placebo in patients with cancer cachexia: A double-blind, randomized, placebo-controlled trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria are: 1. Histologic or cytologic proof evidencing cancers, 2. Incurable malignancy with a life expectancy≥4 months, 3. Weight loss perceived by the patient as a problem, 4. Patient should be alert and mentally competent. Exclusion criteria are: 1. Affliction with edema or ascites, 2. Adrenal corticosteroids treatment (except for dexamethasone during chemotherapy) androgens, progestational agents, or other appetite stimulants within the previous month, 3. Brain metastases, 4. Pregnancy or lactation, 5. Mechanical obstruction of the alimentary tract, 6. Malabsorption, or intractable vomiting, 7. Poorly controlled hypertension or congestive heart failure.

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double 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 Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

City

Isfahan

Postal code

Approval date

2011-08-17, 1390/05/26

Ethics committee reference number

391008

Health conditions studied

1

Description of health condition studied

Malignant neoplasm

ICD-10 code

C80.9

ICD-10 code description

Malignant neoplasm, without specification of site

Primary outcomes

1

Description

arm circumference

Timepoint

before and two months after intervention

Method of measurement

Meter calibrated

2

Description

quality of life

Timepoint

before and two months after intervention

Method of measurement

SF-36 standard questionnaire

Secondary outcomes

1

Description

side effects

Timepoint

during treatment

Method of measurement

clinical observation (nausea / vomiting / tachycardia)

Intervention groups

1

Description

Intervention group will receive Pentoxifylline (400 mg) three times a day.

Category

Treatment - Drugs

2

Description

Control group will receive exactly similar placebo capsules regarding shape, size and taste.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra Hospital

Full name of responsible person
Valiollah Mehrzad

Street address
Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq.

City
Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Isfahan University of medical sciences

Full name of responsible person
Peyman Adibi

Street address
Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq.

City
Isfahan

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, Isfahan 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
Isfahan University of Medical Sciences

Full name of responsible person
Valiollah Mehrzad

Position
Assistant Professor of Oncology

Other areas of specialty/work

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M.D.

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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