

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Evaluation of the Effect of Megestrol Acetate plus Celecoxib in Combination versus Megestrol Acetate alone in Cachexia Induced by Gastrointestinal Cancers

Protocol summary

Summary

Objectives: Evaluation of the effect of megestrol acetate plus celecoxib in combination versus megestrol acetate alone in cachexia induced by gastrointestinal cancers
Design: Triple blind randomized clinical trial
Setting and conduct: 80 eligible patients are randomized into two groups. One group receive megestrol acetate 160 mg BD plus celecoxib 100 mg BD for 2 months. Another group receive megestrol acetate alone 160 mg BD for 2 months.
Major Inclusion criteria: age of more than 18 y; Confirmed diagnosis of gastroesophageal or colorectal cancer in any stage; Hope for survival of at least 4 month; More than 5% weight loss in the past 3 to 6 month or more than 5% weight loss in comparison to the weight before disease or a body weight less than 5% of ideal body weight or a BMI (Body Mass Index) of less than 20; Palliative treatments or chemotherapy is allowed
Major Exclusion criteria: Mechanical obstruction in alimentary tract; Any treatment which induce weight gain like glucocorticoids; Diagnosis of diabetes mellitus with concomitant insulin therapy; Uncompensated cardiac failure with ejection fraction of less than 30% or with New York Heart Association function class of 3 or 4; Uncontrolled Hypertention with systolic blood pressure greater than 140 mmHg or diastolic blood pressure greater than 90 mmHg; History of myocardial infarction; History of unstable angina; History of Cerebro-vascular accidents; Uncontrolled cardiac dysrhythmias ; Inflammatory bowel disease; gastrointestinal ulcers
Intervention: megestrol acetate plus celecoxib in combination versus megestrol acetate alone in cachexia induced by gastrointestinal cancers
Outcome measures (variables) : Body weight, Quality of life, Appetite, Markers of inflammatory response including Interleukin-1, Interleukin-6, Tumor necrotizing factor-alpha and Glasgow prognostic score (GPS) will be measured at base line and at the end of study period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201407222027N4**
Registration date: **2016-09-11, 1395/06/21**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-09-11, 1395/06/21

Registrant information

Name

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Name of organization / entity

Mazandaran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2015-10-10, 1394/07/18

Expected recruitment end date

2016-12-10, 1395/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of Megestrol Acetate plus Celecoxib in Combination versus Megestrol Acetate alone in Cachexia Induced by Gastrointestinal Cancers

Public title

Effect of Megestrol Acetate plus Celecoxib versus Megestrol Acetate alone in Cachexia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Age of more than 18 y; Confirmed diagnosis of gastroesophageal or colorectal cancer in any stage; Hope for survival of at least 4 month; More than 5% weight loss in the past 3 to 6 month or more than 5% weight loss in comparison to the weight before disease or a body weight less than 5% of ideal body weight or a BMI (Body Mass Index) of less than 20; Palliative treatments or chemotherapy is allowed Exclusion criteria: Mechanical obstruction in alimentary tract; Any treatment which induce weight gain like glucocorticoids; Diagnosis of diabetes mellitus with concomitant insulin therapy; Uncompensated cardiac failure with ejection fraction of less than 30% or with New York Heart Association function class of 3 or 4; Uncontrolled Hypertention with systolic blood pressure greater than 140 mmHg or diastolic blood pressure greater than 90 mmHg; History of myocardial infarction; History of unstable angina; History of Cerebro-vascular accidents; Uncontrolled cardiac dysrhythmias; Inflammatory bowel disease; Gastrointestinal ulcers or history of GI bleedings

Age

From **18 years** old to **100 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mazandaran University of Medical Sciences Ethical Committee

Street address

Mazandaran University of Medical Sciences, kilometer 18 of Farah Abad road, Sari, Iran

City

Sari

Postal code

Approval date

2015-08-20, 1394/05/29

Ethics committee reference number

IR.MAZUMS.REC.94-1087

Health conditions studied

1

Description of health condition studied

Cachexia

ICD-10 code

R-64

ICD-10 code description

Cachexia

Primary outcomes

1

Description

Quality of life

Timepoint

2 month from baseline

Method of measurement

EORTC QLQ-C30 questionnaire

2

Description

Weight

Timepoint

2 month from baseline

Method of measurement

Scale with precision of 0.1 Kg

Secondary outcomes

1

Description

IL-1

Timepoint

2 month from baseline

Method of measurement

ELISA

2

Description

IL-6
Timepoint
2 month from baseline
Method of measurement
ELISA

3

Description
TNF-alpha
Timepoint
2 month from baseline
Method of measurement
ELISA

4

Description
Appetite
Timepoint
2 month from baseline
Method of measurement
Visual analogue scale

5

Description
Glasgow prognostic score (GPS)
Timepoint
2 month from baseline
Method of measurement
calculated based on Albumin and CRP

Intervention groups

1

Description
Megestrol acetate 160mg BD+Celecoxib 100mg BD for 2 months in intervention group
Category
Treatment - Drugs

2

Description
Megestrol acetate 160mg BD for 2 months in control group
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Tuba Clinic of Mazandaran University of Medical Sciences
Full name of responsible person
Street address
Tuba Clinic, Khazar Square, Sari

City
Sari

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr Ahmad Ali Enayati
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Research Deputy, Mazandaran university of medical Sciences, Moallem Square, Sari, Iran
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Sari
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mazandaran 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

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Web page address

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