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 Scienses

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 than140 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 Scienses Ethical Committee

Street address
Mazandaran University of Medical Scienses, 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 questionnare

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 Cinic of Mazandaran Univeristy of Medical Scienses
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 Scienses
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 Scienses
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
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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