Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of Metformin impact on the downstaging of rectal cancer patients undergoing neo-adjuvant chemo-radiotherapy

Protocol summary

Study aim

The effect of metformin concomitant use with neo-adjuvant chemo-radiotherapy on the rate of down staging 6 months after treatment in patients with rectal cancer

Design

A clinical trial with a control group, with parallel groups, randomized double-blind, phase 3 on 40 patients, a random number table was used for randomization.

Settings and conduct

• Classification of patients using a random number table into two groups of neo-adjuvant chemoradiotherapy recipients with metformin and placebo . The study is double-blind. Follow-up of patients in both groups at intervals of 1, 3 and 6 months for possible treatment complications, non-recurrent survival, cancer-specific survival and overall survival MRI and biopsy of the rectal mucosa to determine the stage of the tumor and compare with similar cases performed at the beginning of the study

Participants/Inclusion and exclusion criteria

Inclusion : • Having rectal cancer and being a candidate for neo-adjuvant chemo-radiotherapy • Age over 20 and under 70 years Exclusion : Previous history of liver or kidney disease Previous history of moderate to severe heart failure History of MI during the last 6 months

Intervention groups

20 patients with rectal cancer receive 500 mg of metformin daily and 20 patients receive one placebo daily.

Main outcome variables

Evidence of the effectiveness of metformin administration in the incidence of down staging in patients with rectal cancer; the likelihood of local recurrence; overall survival; the probability of success in sphincter preservation surgery; complications from sphincter loss

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170728035349N2**
Registration date: **2022-01-15, 1400/10/25**
Registration timing: **prospective**

Last update: **2022-01-15, 1400/10/25**
Update count: **0**

Registration date

2022-01-15, 1400/10/25

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3344 9443

Email address

zhkarimi@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-29, 1400/11/09

Expected recruitment end date

2023-03-29, 1402/01/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Metformin impact on the downstaging of

rectal cancer patients undergoing neo-adjuvant chemo-radiotherapy

Public title
Evaluation of Metformin impact on the downstaging of rectal cancer patients undergoing neo-adjuvant chemo-radiotherapy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having rectal cancer and being a candidate for neo-adjuvant chemo-radiotherapy Age over 20 and under 70 years
Exclusion criteria:
Previous history of liver or kidney disease Previous history of moderate to severe heart failure History of MI during the last 6 months
Age
From **20 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are randomly assigned to two groups: metformin recipients (group M) and placebo recipients (group P). For this purpose, random block methods with size 2 will be used and the random sequence of this allocation will be generated by STATA16 software.
Blinding (investigator's opinion)
Double blinded
Blinding description
Due to the ambiguity of this study (patients and physicians prescribing the drug are not aware of the main drug and placebo), metformin 500 mg and placebo were indefinitely given to the patient at the end of each radiotherapy session and Its consumption is ensured.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Zanjan University of Medical Sciences
Street address
Zanjan University of Medical Sciences, Faculty of Medical Sciences, Professor Sabouti Blvd.
City
Zanjan
Province
Zanjan
Postal code
4513956184
Approval date
2021-12-01, 1400/09/10
Ethics committee reference number
IR.ZUMS.REC.1400.370

Health conditions studied

1

Description of health condition studied
Rectal Cancer
ICD-10 code
C7A.026
ICD-10 code description
Malignant carcinoid tumor of the rectum

Primary outcomes

1

Description
Down Staging in Rectal Cancer Patients in Neo-adjuvant and Metformin Concomitant Recipients
Timepoint
MRI and biopsy of the rectal mucosa to determine the stage of the tumor and compare with similar cases performed at the beginning of the study, Follow-up of patients in both groups at intervals of 1, 3 and 6 months in terms of possible treatment complications, non-recurrent survival, cancer-specific survival and overall survival
Method of measurement
MRI

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 20 patients in the intervention group receive one metformin 500 tablet daily from Tehran Daroo Company at the same time with 28 sessions of chemoradiotherapy.
Category
Treatment - Drugs

2

Description
Control group: One placebo daily with 28 sessions of chemoradiotherapy
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr hospital
Full name of responsible person
Zhaleh Karimimoghaddam
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zanjan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Zhaleh Karimimoghaddam
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Radiotherapy
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no more information.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available