

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 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

Zanjan University of Medical Sciences

Full name of responsible person

Mazyar Peyda

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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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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