

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Assessment of plasma expression level of the miRNAs involved in chemo-radiotherapy resistance in response to radiotherapy in non-metastatic neoadjuvant rectal cancer patients using microarray technique

Protocol summary

Summary

This study is aimed to investigate the plasma expression level of the miRNAs involved in chemo-radiotherapy resistance in response to radiotherapy in non-metastatic neoadjuvant rectal cancer patients using microarray technique. Inclusion criteria is included 55 patients with locally advanced rectal cancer who referred to Firoozgar hospital and Imam Khomeini hospital of Tehran city from summer 2016 until March 2017. Selection of the patients was done randomly and with the written consent. Then, the patients will receive the radiotherapy with the standard dose of 50 Gy divided to 25 sessions (for 5 weeks, 5 sessions per week). The blood samples (10 cc) will be obtained before the radiotherapy, and 6 weeks and 6 months after the radiotherapy. At the beginning and the end of the study, filling the questionnaire, measuring the height and weight and blood sampling will be done by an expert person. Then, the blood plasmas of 10 patients will be evaluated in order to investigate of the changes of miRNAs using microarray technique, and also the evaluation of other samples will be analyzed using Real-Time PCR method in order to verify the results.

General information

Acronym

microRNA and colorectal cancer

IRCT registration information

IRCT registration number: **IRCT2016072618745N9**

Registration date: **2016-07-29, 1395/05/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-07-29, 1395/05/08

Registrant information

Name

Ali Mohammad Alizadeh

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2501

Email address

aalizadeh@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of plasma expression level of the miRNAs involved in chemo-radiotherapy resistance in response to radiotherapy in non-metastatic neoadjuvant rectal cancer patients using microarray technique

Public title

Assessment of plasma expression level of some factors involved in chemo-radiotherapy resistance in response to radiotherapy in non-metastatic rectal cancer patients

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: Patient with locally advanced rectal cancer; Patient with non-metastatic rectal cancer
Exclusion criteria: Patients with other cancers; Patients with renal and hepatic disorders

Age

No age limit

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: 55

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Keshavarz Bulvar, Porsina Street

City

Tehran

Postal code

Approval date

2016-04-10, 1395/01/22

Ethics committee reference number

IR.IUMS.REC.1394/19753

Health conditions studied

1

Description of health condition studied

locally advanced rectal cancer

ICD-10 code

C20

ICD-10 code description

Malignant neoplasm of rectum

Primary outcomes

1

Description

the alteration of plasma expression level of the miRNAs

Timepoint

before and after irradiation

Method of measurement

microarray technique

Secondary outcomes

1

Description

plasma expression level of the genes

Timepoint

before and after irradiation

Method of measurement

Real-time PCR

Intervention groups

1

Description

The patients will receive the radiotherapy with the standard dose of 50 Gy divided to 25 sessions (for 5 weeks, 5 sessions per week). The blood samples (10 cc) will be obtained before the radiotherapy, and 6 weeks and 6 months after the radiotherapy, and then the blood plasma will be separated.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Cancer Research Center, Cancer Institute of Iran

Full name of responsible person

Dr. Ali Mohammad Alizadeh

Street address

3rd Fl. of Radiotherapy Bldg, Cancer Institute, Imam Khomeini Hospital, Keshavarz Boulevard, Tehran, Iran

City

Tehran

2

Recruitment center

Name of recruitment center

Firoozgar Hospital

Full name of responsible person

Dr. Farhad Zamani

Street address

Firoozgar Hospital, Behafarin St., Karimkhanzand St., Vali-E-Asr Sq.

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Tehran University of
Medical Sciences

Full name of responsible person
Dr. Uonesian

Street address
Keshavarz Bulvar, Porsina Street.

City
Tehran

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, Tehran 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
Cancer Research Center, Cancer Institute of Iran

Full name of responsible person
Dr. Ali Mohammad Alizadeh

Position
Assistant Professor

Other areas of specialty/work

Street address
3rd Fl. of Radiotherapy Bldg, Cancer Institute, Imam
Khomeini Hospital, Keshavarz Boulevard, Tehran, Iran

City
Tehran

Postal code

Phone
+98 21 6119 2501

Fax

Email
aalizadeh@sina.tums.ac.ir

Web page address
www.pccrg.org

Person responsible for scientific inquiries

Contact

Name of organization / entity
Cancer Research Center, Cancer Institute of Iran

Full name of responsible person
Dr. Ali Mohammad Alizadeh

Position
Assistant Professor

Other areas of specialty/work

Street address
3rd Fl. of Radiotherapy Bldg, Cancer Institute, Imam
Khomeini Hospital, Keshavarz Boulevard, Tehran, Iran

City
Tehran

Postal code

Phone
+98 21 6119 2501

Fax

Email
aalizadeh@sina.tums.ac.ir

Web page address
www.pccrg.org

Person responsible for updating data

Contact

Name of organization / entity
Cancer Research Center, Cancer Institute of Iran

Full name of responsible person
Dr. Ali Mohammad Alizadeh

Position
Assistant Professor

Other areas of specialty/work

Street address
3rd Fl. of Radiotherapy Bldg, Cancer Institute, Imam
Khomeini Hospital, Keshavarz Boulevard, Tehran, Iran

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Fax

Email
aalizadeh@sina.tums.ac.ir

Web page address
www.pccrg.org

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