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
befor and after irradation
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
City
Tehran
Postal code
Phone
+98 21 6119 2501
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