

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Radioprotective effect of melatonin on preventing of cancer-related thrombocytopenia in patient with rectal cancer

Protocol summary

Summary

In this quasi-experimental study is a double blind, in order to investigate the protective effect of melatonin radiation, 60 patients ranging in age from 40 to 60 years of age and have the same radiation dose and regimen of chemotherapy and surgery is still not done, the study data are. Patients selected for the study protocol for the regime fu-5 350mg / m² plus leucovorin 20mg / m², which first group of one to five days from 23 to 28 chemotherapy treatment and in total 28 radiotherapy day and an hour daily for 5 days per week before radiation therapy received 20 mg of melatonin and the second group one hour daily for 5 days per week before radiation therapy of 20 mg receive wholemeal flour. Blood samples taken before treatment and after treatment and the number of platelets be counted and compared with each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016021626586N1**

Registration date: **2016-03-03, 1394/12/13**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-03-03, 1394/12/13

Registrant information

Name

Nasim Kouhi Habibi Dehkordi

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3219 9592

Email address

n.kouhi@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Babol University of Medical Sciences

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2017-03-18, 1395/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Radioprotective effect of melatonin on preventing of cancer-related thrombocytopenia in patient with rectal cancer

Public title

Radioprotective effect of melatonin in patient with rectal cancer

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 60 patients with rectal cancer; aged 40 to 60 years with radiotherapy and chemotherapy same regime that still have not done surgery Exclusion criteria: patients with autoimmune diseases (purpura); von Willebrand's disease; patients that of aspirin drugs; sulfadiazine; daunorubicin use; individuals who previously had chemotherapy or radiotherapy; people who have a history of depression or suicidal feeling

Age

From **40 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Babol University of Medical Sciences

Street address

Babol-Gang afrooz Street

City

Babol

Postal code**Approval date**

2015-09-08, 1394/06/17

Ethics committee reference number

UBABOL.REC.1394.154

Health conditions studied**1****Description of health condition studied**

rectal cancer

ICD-10 code

D12.8

ICD-10 code description

Benign neoplasm: Rectum

2**Description of health condition studied**

radiation injury

ICD-10 code

W88

ICD-10 code description

Exposure to ionizing radiation

Primary outcomes**1****Description**

thrombocytopenia

Timepoint

before beginning treatment and at the end of treatment

Method of measurement

CBC

Secondary outcomes**1****Description**

thrombocytopenia

Timepoint

before beginning treatment and at the end of treatment

Method of measurement

CBC

Intervention groups**1****Description**

Melatonin capsules containing 20 mg daily administered 1 hour before radiation therapy 5 days a week for 28 days

Category

Prevention

2**Description**

Administration of a capsule containing 20 mg per day 5 days per week wholemeal flour 1 hour before radiation therapy for 28 days.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Rajai Hospital of Babolsar

Full name of responsible person

Dr. Ali Shabestani Monfared

Street address

Shilat Square, Babolsar

City

Babolsar

Sponsors / Funding sources**1****Sponsor**

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Dr. Aliakbar Moghadamnia

Street address
Deputy of research and technology, Babol University of Medical Sciences, Babol

City
Babol

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Babol 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
Babol University of Medical Sciences

Full name of responsible person
Nasim Kouhi Habibi Dehkordi

Position
Msc of radiationbiology

Other areas of specialty/work

Street address
Medical School, Babol University of Medical Sciences, Babol

City
Babol

Postal code

Phone
+98 11 3219 9592

Fax

Email
n.kouhi@mubabol.ac.irkouhi.nasim@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person
Dr. Ali Shabestani Monfared

Position
PhD in Medical Physics

Other areas of specialty/work

Street address
Department of Biophysics, Babol University of Medical Sciences, Babol

City
Babol

Postal code

Phone
+98 11 3219 9592

Fax

Email
Monfared1345@gmail.com Monfared_ali@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Nasim Kouhi Habibi Dehkordi

Position
Msc of Radiationbiology

Other areas of specialty/work

Street address
Babol University of Medical Sciences, Babol

City
Babol

Postal code

Phone
00

Fax

Email
kouhi.nasim@gmail.comn.kouhi@mubabol.ac.ir

Web page address

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