

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

The investigation radioprotective effect against DNA double-stranded breaks induced in Peripheral blood lymphocytes of patients undergoing CT examinations of the abdomen/pelvic of melatonin by immunofluorescence assay

Protocol summary

Study aim

If melatonin administration is able to reduce double strand break (DSB) induced by radiation from computed tomography (CT-scan), ingestion of melatonin before irradiation can be recommended to patients.

Design

A total of 30 patients scheduled for abdomen/pelvic CT examinations will be randomly divided into two groups (15 patients in each). In one group, 5 cc of blood will be taken from each of them before and after exposure to radiation. In the other group, 100 mg of melatonin will be administered orally 1 hour before exposure to radiation. 30 minutes after irradiation, 5 cc of blood will be collected. Written informed consent will be obtained from each patient before commencement of these procedures.

Settings and conduct

Patients scheduled for abdomen and pelvic CT Scan will be conducted at Shahid Beheshti Hospital, Shiraz while immunofluorescence experiments will be carried out at Novin Medical Radiation Institute, Tehran.

Participants/Inclusion and exclusion criteria

Range of age is between 25 to 60 years, as well as non-smoker, non-athlete and non-alcoholic, with no history of chemotherapy and radiotherapy.

Intervention groups

15 patients will be administered 100 mg of melatonin 1 hour before exposure to radiation.

Main outcome variables

If melatonin administration is able to reduce DSB induced by CT-scan, ingestion of melatonin before irradiation can be recommended to patients.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171122037593N1**

Registration date: **2019-03-13, 1397/12/22**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-13, 1397/12/22**

Update count: **0**

Registration date

2019-03-13, 1397/12/22

Registrant information

Name

farid esmaely

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8875 0763

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-10, 1397/12/19

Expected recruitment end date

2019-04-20, 1398/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The investigation radioprotective effect against DNA

double-stranded breaks induced in Peripheral blood lymphocytes of patients undergoing CT examinations of the abdomen/pelvic of melatonin by immunofluorescence assay

Public title

Using melatonin pill to reduce the risk of cancer due to exposure to radiation doses from CT imaging .

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

healthy person non-athlete non-smoker non-alcoholic no-radiation therapy no- history of chemotherapy

Exclusion criteria:

smoker alcoholic having radiation therapy having chemotherapy

Age

From **25 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **2**

5 cc blood is taken before taking the pill and 5 cc of blood will be taken after 1 hour and a half after taking the pill

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be provided with a computer-generated randomization list by a statistical consultant, and an out-of-site person who does not know about the study will give patients with melatonin and placebo on the list.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients will be provided with a computer-generated randomization list by a statistical consultant, and an out-of-site person who does not know about the study will give patients with melatonin and placebo on the list. The collection of blood samples and preparation of lam will be done by the main investigator, but the coded lam will be given to read the DNA damage to a specialist who does not know these codes and groupings (as compared to the blind slamming code).

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Tehran University of Medical Sciences, Tehran, Iran.

Street address

Building no.1, Northern gate of the University, Poursina St. Qods St. Enqelab St.Tehran.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2018-05-15, 1397/02/25

Ethics committee reference number

IR.TUMS.VCR.REC.1397.022

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

...

ICD-10 code

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ICD-10 code description

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

gamma-h2ax foci per cell that represent double strand break(DSB) in cell

Timepoint

Counting the number of DSB in the control group at zero time without taking melatonin and also 1 hour before radiation

Method of measurement

Using the immune fluorescence assay, using gamma-h2ax antibodies and fluorescence microscopy, the number of gamma-h2ax foci is counted.

Secondary outcomes

empty

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

Control group: Patients will be administered only radiation from CT scan and no additional procedures will be done.

Category

N/A

2

Description

Intervention group: This group will be administered two 50 mg tablets of melatonin 1 hour before imaging, before exposure to radiation from CT scans.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital CT-scan section

Full name of responsible person

Ali Escandary

Street address

Zeynabiyeh Blvd Vali Asr Square

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/

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Ali Reza Shirazi

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

DR Ali Reza Shirazi

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

Radiobiology and Radio safety

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Only age and gender will be available to everyone.

When the data will become available and for how long

From 2019.

To whom data/document is available

Just researcher at universities

Under which criteria data/document could be used

There are no specific data other than age.

From where data/document is obtainable

Refer to Mr Eskandari

What processes are involved for a request to access data/document

After an email, some can have the age of people and gender

Comments

Due to the fact that patients are not given specific information other than age and written informed consent, there is no need to publish specific information.