Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The investigation radioprotective effect against DNA double-stranded breaks induced in Peripheral blood lymphocytes of patients undergoing CT examinations of the abdomenpelvic 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 inform 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 be conducted at Shahid Beheshti Hospital, Shiraz while immunofluorescence experiments will be carried out at Novin Medical Radiation Instituite, 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)

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+98 21 8875 0763

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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 abdomenpelvic 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
.
ICD-10 code description
.

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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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.