

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Evaluation of nephroprotective effects of Melatonin in cancer patients treated with Cisplatin

Protocol summary

Study aim

Evaluation of Melatonin protective effects on the Cisplatin nephrotoxicity by kidney injury molecule-1 (Kim-1) , Neutrophil gelatinase-associated lipocalin (NGAL) and serum creatinine measurement.

Design

Randomized, double-blinded, parallel, placebo-controlled clinical trial with 25 patients in each group.

Settings and conduct

This double blind study will be done in order to evaluation of nephroprotective effects of Melatonin by NGAL , KIM-1 and serum creatinine measurement . Researcher and patients are blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: ≥ 18 years of age Cancer patients who receive Cisplatin with ≥ 50 mg/m² of dose in one day and the chemotherapy courses are repeated every 3 weeks Patients with one of lung, head and neck, genitourinary system, gastrointestinal cancers Glomerular filtration rate (GFR) >45 ml/min (modification of diet in renal disease (MDRD) formula) Exclusion criteria: Patients with kidney cancer The history of using other nephrotoxic drugs within the previous 2 weeks

Intervention groups

Treatment group: patients who receive Melatonin Control group: patients who receive placebo

Main outcome variables

Urine NGAL , urine KIM_1 , urine creatinine and serum creatinine and BUN

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171225038073N1**

Registration date: **2018-08-30, 1397/06/08**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-30, 1397/06/08**

Update count: **0**

Registration date

2018-08-30, 1397/06/08

Registrant information

Name

Elliyeh Ghadrnan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6609 9223

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el-ghadrnan@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of nephroprotective effects of Melatonin in cancer patients treated with Cisplatin

Public title

Evaluation of nephroprotective effects of Melatonin

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

≥ 18 years of age Cancer patients who receive Cisplatin

with ≥ 50 mg/m² of dose in one day and the chemotherapy courses are repeated every 3 weeks
Patients who do not use other nephrotoxic chemotherapy drugs
Glomerular filtration rate (GFR) > 45 ml/min
(modification of diet in renal disease (MDRD) formula)
Patients with one of lung, head and neck, genitourinary system, gastrointestinal cancers
Karnofsky status $\geq 60\%$
Normal liver function

Exclusion criteria:

Kidney cancer
Inability to take oral medication
Heart failure
Active infection
The history of using other nephrotoxic drugs (e.g. Vancomycin, Aminoglycoside, Amphotericin and NSAID) within the previous 2 weeks
The patients who are using angiotensin-converting-enzyme inhibitor (ACE inhibitor) & angiotensin receptor blockers (ARB) medicines

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: block randomization
Unit of randomization: individualized
Randomization by statistical software
Allocation concealment : numbered drug containers

Blinding (investigator's opinion)

Double blinded

Blinding description

Researcher and data collector: blinded because the researcher is unaware of the contents of the can
Patients: blinded because they are unaware of the contents of the can
Health care personnel: blinded because they are unaware of the contents of the can
Data analyser: unblinded
Writer of the article draft: blinded

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of the institute of pharmaceutical sciences
Tehran university of medical sciences

Street address

Tehran university of medical sciences

City

Tehran

Province

Tehran

Postal code

0

Approval date

2018-04-23, 1397/02/03

Ethics committee reference number

IR.TIPS.REC.1397.016

Health conditions studied

1

Description of health condition studied

Lung, head and neck, genitourinary system or gastrointestinal cancers

ICD-10 code

C7, C8 ,

ICD-10 code description

C07 Malignant neoplasm of parotid gland , C08 Malignant neoplasm of other and unspecified major salivary glands, C09 Malignant neoplasm of tonsil , C10 Malignant neoplasm of oropharynx, C11 Malignant neoplasm of nasopharynx, C12 Malignant neoplasm

Primary outcomes

1

Description

Urine Neutrophil gelatinase-associated lipocalin (NGAL) level

Timepoint

Urine NGAL level measurement dose before Cisplatin administration , 6 h and 24 h after

Method of measurement

Enzyme-linked immunosorbent assay (ELISA) method

2

Description

Urine Kidney Injury Molecule-1 (KIM-1) level

Timepoint

Urine KIM1 level measurement dose before Cisplatin administration , 6 h and 24 h after

Method of measurement

Enzyme-linked immunosorbent assay (ELISA) method

3

Description

Serum creatinine level

Timepoint

Serum creatinine level measurement dose before Cisplatin administration and 72 h after

Method of measurement

Jaffe method

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Melatonin with dose of 20 mg (two Melatonin 10 mg tablets) from Best naturals company will be prescribed every night from at least 1 day before Cisplatin administration to one week period.

Category

Prevention

2

Description

Control group: Two tablet of Placebo will be prescribed every night from at least 1 day before Cisplatin administration to one week period.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

cancer institute of Imam Khomeini hospital

Full name of responsible person

Zahra Jahangard Rafsanjani

Street address

Keshavarz Ave., Imam Khomeini hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Grant name

Research committee of Tehran university of medical sciences

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

Zahra Jahangard-Rafsanjani

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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Name of organization / entity

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The data like patient lab data and effects of Melatonin and side effects of chemotherapy will be published in form of article

When the data will become available and for how long

At the end of study and after publication

To whom data/document is available

Scientific researchers

Under which criteria data/document could be used

For more researches

From where data/document is obtainable

Zahra Jahangard-Rafsanjani

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

After acceptance by Zahra Jahangard-Rafsanjani

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Elliyeh Ghadrddan

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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