Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Kidney-protective Effect of Magnesium Supplementation in Carboplatin-containing Chemotherapy for Pediatric Cancer

Protocol summary

Study aim
The effect of magnesium on nephrotoxicity of Carboplatin
Design
Randomized, not blinded, controlled clinical trial with a parallel group design of 25 patients in each group
Settings and conduct
This study is performed as an intervention on children with malignant carboplatin who are hospitalized in Amirkabir Hospital in Arak. Patients who meet the criteria for entry into the study based on the diagnosis of an oncologist are initially given conscious consent to participate in the study. The effects of carboplatin, its renal toxicity, and the possible effect of magnesium on reducing renal toxicity to patients are then explained by the researcher (medical student) and entered into the study after ensuring complete patient satisfaction and awareness. Patients receiving carboplatin by coin toss (milk for the intervention group and line for the control group) are randomly divided into two groups receiving Mg + magnesium supplement and not receiving Mg- magnesium. In this study, patients' creatinine, GFR and BUN levels were measured before receiving carboplatin. The creatinine, GFR and BUN levels of both groups will be measured on the third day, one week after the end of chemotherapy.
Participants/Inclusion and exclusion criteria
Inclusion criteria: Children over 2 years of age with malignancy receiving Carboplatin Exclusion criteria: Renal impairment with GFR <30, administration of platinum or other nephrotoxic drugs, antibiotic administration
Intervention groups
Control group: Patients receive placebo tablet for two weeks each day before Carboplatin therapy. Intervention group: Patients receive magnesium oxide 250 mg tablet for two weeks each day before Carboplatin therapy.
Main outcome variables
Creatinine serum level, blood urea nitrogen and glomerular filtration rate

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190619043948N1**
Registration date: **2020-04-11, 1399/01/23**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-11, 1399/01/23**
Update count: **0**
Registration date
2020-04-11, 1399/01/23

Registrant information
Name
Marzie Alizade Hadadhania
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 28 3333 7711
Email address
marzie.alizade@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-11-06, 1398/08/15
Expected recruitment end date
2020-05-04, 1399/02/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date

empty

Scientific title
Kidney-protective Effect of Magnesium Supplementation in Carboplatin-containing Chemotherapy for Pediatric Cancer

Public title
Effect of magnesium on Nephrotoxicity of Carboplatin
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Children over 2 years of age with malignancy receiving Carboplatin
Exclusion criteria:
Kidney disorder with GFR under 30 Receiving other platinum drugs or other nephrotoxic drugs Receiving antibiotics
Age
From **2 years** old to **16 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
At the beginning of the study, the demographic data collection form will be completed, and if you have the conditions to enter the study of patients receiving carboplatin by coin toss (heads for the intervention group and tails for the control group) randomly, to the two groups receiving magnesium supplement Mg + And do not receive Mg-magnesium.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak University of Medical Sciences
Street address
No. 17, Sahand Deadend, Sepidar Alley, Naderi Sholmali Ave.
City
arak
Province
Markazi
Postal code
3413719451
Approval date
2019-08-04, 1398/05/13
Ethics committee reference number
IR.ARAKMU.REC.1398.086

Health conditions studied

1

Description of health condition studied
Nephrotoxicity of Carboplatin
ICD-10 code
N14.1
ICD-10 code description
Nephropathy induced by other drugs, medicaments and biological substances

Primary outcomes

1

Description
Blood urea nitrogen
Timepoint
Before intervention and 2 and 7 days later
Method of measurement
Mass spectrometry

2

Description
Creatinine
Timepoint
Before intervention and 3 and 7 days later
Method of measurement
Mass spectrometry

3

Description
Glomerular filtration rate
Timepoint
Before intervention and 3 and 7 days later
Method of measurement
Schwartz formula, by calculation

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Patients receive placebo tablet (Jalinus brand) orally for two weeks each day before Carboplatin therapy.

Category

Placebo

2

Description

Intervention group: Patients receive magnesium oxide 250 mg tablet (Jalinus brand) orally for two weeks each day before Carboplatin therapy.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amikabir hospital

Full name of responsible person

Marzie Alizade Hadadhania

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No. 17, Sahand Deadend, Sepidar Alley, Naderi Shomali Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Marzie Alizade Hadadhania

Position

Medical Student (Intern)

Latest degree

A Level or less

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available