

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 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 Hadadthania

##### 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 Hadadhanian

**Street address**

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

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**Province**

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**Postal code**

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**Phone**

+98 28 3333 7711

**Email**

marzie.alizade@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Marzie Alizade Hadadhanian

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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 Hadadhanian

**Position**

Medical Student (Intern)

**Latest degree**

A Level or less

**Other areas of specialty/work**

Pediatrics

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**Contact**

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**Latest degree**

A Level or less

**Other areas of specialty/work**

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**City**

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**Province****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