

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Clinical trial of oral magnesium oxide supplementation in prevention of cisplatin-induced hypomagnesaemia in cancer patients in Rasoul Akram hospital of Tehran university of medical sciences

Protocol summary

Summary

Hypomagnesaemia is one of the side effects of Cisplatin which is used in cancer patients who undergo treatment with regimens containing this drug. Cisplatin causes a defect in magnesium homeostasis because of its effects on tubular reabsorption of magnesium in the kidneys and tubular necrosis. Magnesium deficiency can cause some symptoms such as neurological- muscle disorders, mental disorders, electrocardiographic changes and even sudden death because of tetany or heart attack. The aim of this study is to assess the effect of magnesium oxide supplement on prevention of hypomagnesaemia in cancer patients receiving Cisplatin. In this study 80 cancer patients who are candidate for therapy with Cisplatin containing regimen in Rasoul Akram hospital will be selected. Inclusion criteria are: absence of renal disease, alcoholism and leukemia, not on diuretic, aminoglycosides, cyclosporine and amphotericin B. The only exclusion criterion is: death before end of treatment. Patients will be divided in two groups (intervention and control) randomly. Patients in intervention group will receive magnesium oxide supplement (21CENTURY magnesium oxide 250 mg tablet) according to Cisplatin dose (500 mg/day magnesium oxide for each 50/m² of Cisplatin) during interval days between chemotherapy courses. Patients in control group do not receive any supplement. Patients' serum levels of magnesium, calcium, potassium, sodium, urea and creatinin are measured before each chemotherapy courses.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112048299N1**
Registration date: **2012-08-13, 1391/05/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-08-13, 1391/05/23

Registrant information

Name

Masoud Vakili

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8873 4239

Email address

m-vakili@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Oncopathology Research Center of Tehran University of Medical Sciences

Expected recruitment start date

2009-12-06, 1388/09/15

Expected recruitment end date

2012-03-05, 1390/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of oral magnesium oxide supplementation in prevention of cisplatin-induced hypomagnesaemia in

cancer patients in Rasoul Akram hospital of Tehran
university of medical sciences

Public title

Magnesium supplementation in cancer patients under
cisplatin treatment

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: cancer diagnosis, beginning
chemotherapy with Cisplatin drug, absence of renal
disease and alcoholism, leukemia, non-consumption of
drugs such as diuretics, aminoglycosides, cyclosporine
and amphotericin B Exclusion criteria: death before end
of treatment

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Oncopathology Research Center, Ethics Committee of
Tehran University of Medical Sciences

Street address

Oncopathology Research Center of Tehran University
of Medical Sciences, First floor, Medical College,
between Sheikh Fazlolahe Noori Exp. and Chamran
Exp., Hemmat Exp., Tehran

City

Tehran

Postal code**Approval date**

2009-12-07, 1388/09/16

Ethics committee reference number

361/ت م

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

Hypomagnesaemia

ICD-10 code

E83.4

ICD-10 code description

Hypomagnesaemia (Disorders of magnesium metabolism)

2**Description of health condition studied**

Cancer types

ICD-10 code

C00-C14, C

ICD-10 code description

Malignant neoplasms of lip, oral cavity and pharynx,
Malignant neoplasms of digestive organs, Malignant
neoplasms of respiratory and intrathoracic organs,
Malignant neoplasms of bone and articular cartilage,
Malignant neoplasms of mesothelial and soft tis

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

Serum magnesium level

Timepoint

Before starting every course of chemotherapy

Method of measurement

Biochemical analysis

Secondary outcomes**1****Description**

Serum Creatinin level

Timepoint

Before starting every course of chemotherapy

Method of measurement

Biochemical analysis

2**Description**

Serum Urea level

Timepoint

Before starting every course of chemotherapy

Method of measurement

Biochemical analysis

3**Description**

Serum Calcium level

Timepoint

Before starting every course of chemotherapy

Method of measurement

4

Description

Serum Potassium level

Timepoint

Before starting every course of chemotherapy

Method of measurement

Biochemical analysis

5

Description

Serum Sodium level

Timepoint

Before starting every course of chemotherapy

Method of measurement

Biochemical analysis

Intervention groups

1

Description

Patients in intervention group got magnesium oxide supplement (21CENTURY magnesium oxide 250 mg tablet)* according to Cisplatin dose (for Cisplatin dose up to 50 mg/m², 500 mg/day magnesium oxide, for Cisplatin dose: 50-100 mg/m², 1000 mg/day magnesium oxide, for Cisplatin dose more than 100 mg/m², 1500 mg/day magnesium oxide) during interval days between chemotherapy courses. * 21Century HealthCare, Inc., USA

Category

Prevention

2

Description

Patients in control group did not get any supplement.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram Hospital of Tehran University of Medical Sciences

Full name of responsible person

Dr. Masoud Vakili

Street address

Rasoul Akram Hospital of Tehran University of Medical Sciences, Niayesh St., Sattarkhan St., Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oncopathology Research Center of Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohsen Asadi Lari

Street address

Oncopathology Research Center of Tehran University of Medical Sciences, First floor, Medical College, between Sheikh Fazlolahe Noori Exp. and Chamran Exp., Hemmat Exp., Tehran

City

Tehran

Grant name

1519033

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Oncopathology Research Center of Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Research Institute for Endocrine Sciences of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maryam Zarif Yeganeh

Position

MSc of Nutrition Sciences

Other areas of specialty/work

Street address

Research Institute for Endocrine Sciences of Shahid Beheshti University of Medical Sciences, No. 24, Parvaneh St., Yaman St., Chamran Exp., Tehran

City

Tehran

Postal code

Phone

+98 21 2243 2503

Fax

Email

m_zarifeyeganeh@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rasoul Akram Hospital of Tehran University of Medical Sciences

Full name of responsible person

Dr. Masoud Vakili

Position

Hematology and Oncology Specialist, MD

Other areas of specialty/work**Street address**

Rasoul Akram Hospital of Tehran University of Medical Sciences, Niayesh St., Sattarkhan St., Tehran

City

Tehran

Postal code**Phone**

+98 21 6435 2390

Fax**Email**

m-vakili@sina.tums.ac.ir m_zarifyeganeh@yahoo.com
masvak@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Research Institute for Endocrine Sciences of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maryam Zarif Yeganeh

Position

MSc of Nutrition Sciences

Other areas of specialty/work**Street address**

Research Institute for Endocrine Sciences of Shahid Beheshti University of Medical Sciences, No. 24, Parvaneh St., Yaman St., Chamran Exp., Tehran

City

Tehran

Postal code**Phone**

+98 21 2243 2503

Fax**Email**

m_zarifyeganeh@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty