Mechanism of cisplatin induced hypomagnesemia

Published: 14-01-2010
Last updated: 04-05-2024

To study the mechanism of cisplatin induced hypomagnesemia.To identify predisposing factors for cisplatin induced hypomagnesemia.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON33071

Source
ToetsingOnline

Brief title
Cisplatin hypomagnesemia

Condition

- Other condition
- Miscellaneous and site unspecified neoplasms benign

Synonym
Hypomagnesemia = low serum magnesium concentration

Health condition

electrolytstoornissen

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: 17-beta-estradiol, Endothelial growth factor, Oncology, Urinary magnesium excretion

Outcome measures

Primary outcome

Factors associated with hypomagnesemia, including 24-hour urinary magnesium,

erythrocyte magnesium levels, 17-β-estradiol, endothelial growth factor,

acid-base balance.

Secondary outcome

Differences between patients with and without hypomagnesemia (patient

characteristics, underlying disease, chemotherapy characteristics, laboratory

values)

Study description

Background summary

Cisplatin is a potent and valuable platinum-based chemotherapeuritc agent used to treat a broad spectrum of malignancies. Cisplatin can cause hypomagnesemia, sometimes permanently and with an estimated prevalence of roughly 50%. In recent years, the renal handling of magnesium has been largely elucidated, especially through the identification of TRPM6, a magnesium channel. In addition, although no single hormone for magnesium regulation has been identified, other regulatory factors have become clear. These include 17-β-estradiol, the endothelial growth factor, acidosis, and alkalosis. It is important to emphasize that the serum magnesium level may not be a good estimate of total body magnesium. Instead, a better parameter may be the magnesium concentration in the erythrocyte. The exact mechanism of cisplatin induced hypomagnesemia is unknown. In addition, the new insights regarding

magnesium metabolism described above have not been studied in the context of cisplatin induced hypomagnesemia. Therefore, we intend to study cisplatin induced hypomagnesemia in oncological patients who receive cisplatin as monotherapy.

Study objective

To study the mechanism of cisplatin induced hypomagnesemia.
To identify predisposing factors for cisplatin induced hypomagnesemia.

Study design

Prospective observational pilot study

Study burden and risks

Burden: 5-12 urine collections extra for study, 2-6 blood withdrawals extra for study, 3-6 questionnaires extra for study (numbers depend on the exact chemotherapy scheme).
Risk: blood withdrawal (pain, hematoma, vasovagal syncope).
Benefit: serum magnesium levels are checked frequently. If disturbed, this will be treated, which is a potential benefit for the patients participating in the study.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Postbus 2040
3000 CA Rotterdam
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Postbus 2040
3000 CA Rotterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All oncological patients who are selected for monotherapy with cisplatin.

Exclusion criteria

None.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2009
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO Date:	14-01-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL29216.078.09