Intracellular levels of magnesium and phosphate in patients with renal hypomagnesemia and hypophosphatemia: a pilot observational study

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- To evaluate the effect of magnesium and phosphate supplementation on intracellular levels of magnesium and phosphate determined with different techniques.- To determine if symptoms are related to intracellular levels of magnesium or phosphate.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Nephropathies
Study type	Observational invasive

Summary

ID

NL-OMON49432

Source
ToetsingOnline

Brief title
Intracellular Mg and PO4 in renal hypomagnesemia and hypophosphatemia

Condition

- Nephropathies

Synonym
Hypomagnesemia/hypophosphatemia, low blood magnesium/phosphate, low serum magnesium/phosphate

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Hypomagnesemia, Hypophosphatemia, Intracellular magnesium, Intracellular phosphate

Outcome measures

Primary outcome

Intracellular levels of magnesium or phosphate in erythrocytes, peripheral

blood mononuclear cells and skeletal muscle before and after supplementation of

magnesium and phosphate

Secondary outcome

- Serum magnesium or phosphate

- Personalized symptom score sheet

- ATP levels in skeletal muscle cells (measured by 31P NMR)

Study description

Background summary

Magnesium and phosphate are electrolytes that mainly reside intracellularly. Both electrolytes have an important intracellular role, they are for instance involved in intracellular cell signalling and energy metabolism. The kidney is an important regulator of magnesium and phosphate homeostasis. Disturbances in this regulation can lead to renal wasting of magnesium or phosphate, causing hypomagnesemia or hypophosphatemia.
Patients with renal hypomagnesemia and hypophosphatemia suffer from symptoms such as fatigue, muscle weakness and paraesthesia. Treatment consists of supplementation therapy. However, despite normalization or near normalization of serum magnesium or phosphate, some patients remain symptomatic. This might be because of a intracellular deficit of magnesium or phosphate. Serum magnesium and phosphate are probably not a good parameter of depletion of

magnesium and phosphate.
We hypothesize that intracellular levels of magnesium, phosphate and/or possibly ATP are better parameters for the assessment of magnesium and phosphate depletion than serum levels. Also, we assume that symptoms are more related to intracellular levels of magnesium and phosphate than serum levels.

Study objective

- To evaluate the effect of magnesium and phosphate supplementation on intracellular levels of magnesium and phosphate determined with different techniques.
- To determine if symptoms are related to intracellular levels of magnesium or phosphate.

Study design

A pilot observational diagnostic test study

Study burden and risks

Patients will receive their regular treatment. Investigational tests will be performed during regular outpatient clinic visits or during a planned regular admission to our inpatient ward. An additional blood sample will be drawn when a venapuncture was already scheduled in the context of regular treatment. A MRI-scan will be performed, this is a non-invasive procedure without complications. Also patients will have to fill out a personalized symptom questionnaire.

Contacts

Public
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 8
Nijmegen 6525GA
NL
Scientific
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 8
Nijmegen 6525GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Symptomatic renal hypomagnesemia or hypophosphatemia
- Patient is about to start with regular supplementation therapy (oral or intravenous supplementation) or therapy is planned to be intensified based on insufficient response on the previous treatment (increasing oral supplementation or addition of intravenous supplementation on top of oral supplementation)
- Age >= 16 years
- Informed consent

Exclusion criteria

- patients who are pregnant at time of inclusion

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-03-2021
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	01-04-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL72523.091.20