FGF23 response in hypophosphatemia

Published: 18-07-2016
Last updated: 16-04-2024

to determine the normal FGF23 response in case of hypophosphatemia

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Nephropathies
Study type	Interventional

Summary

ID

NL-OMON42928

Source
ToetsingOnline

Brief title
FGF23 response in hypophosphatemia

Condition

- Nephropathies

Synonym
hypophosphatemia, low bood phosphate level

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: subsidie college zorgverzekeringen

Intervention

Keyword: FGF23, phosphate

Outcome measures

Primary outcome

The main study parameter is the level of FGF23 at phosphate levels below 0.50

mmol/l

Secondary outcome

PTH levels

Study description

Background summary

Hypophosphatemia due to renal phosphate wasting can be the consequence of a long list of both acquired and inherited disorders. An important differential diagnosis is tumour induced osteomalacia (TIO), mostly caused by FGF23 producing mesenchymal tumours. The main problem in the evaluation of patients with renal phosphate wasting however is the interpretation of FGF23 levels. It is suggested that hypophosphatemia itself should lower FGF23 levels but this is never systematically studied.

Study objective

to determine the normal FGF23 response in case of hypophosphatemia

Study design

prospective intervention study in which healthy volunteers will receive lanthanum carbonate until they develop a hypophosphatemia of <0.50 mmol/l.

Intervention

lanthanum carbonate

Study burden and risks

participants risk developing symptoms related to hypophosphatemia such as general body weakness and neuromuscular complaints. this will only be for a short period as the lanthanum carbonate will bes stopped as soon a

hypophosphatemia is accomplished.

Contacts

Public
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 8 Geert Grooteplein Zuid 8
6500 HB Nijmegen 6500 HB
NL
Scientific
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 8 Geert Grooteplein Zuid 8
6500 HB Nijmegen 6500 HB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

age * 18 years

Exclusion criteria

* any medical history
* inability to give informed consent
* pregnancy

* medication use (except for oral anti contraceptives)

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-06-2019
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	lanthanum carbonate
Generic name:	fosrenol
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	18-07-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	25-08-2016
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
EudraCT	EUCTR2016-002602-39-NL
CCMO	NL57379.091.16