Role of different phosphate binders on absorption of vitamin K, metabolism of matrix *-carboxy-glutamaat (Gla) proteïne (MGP).

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON44005

Source
ToetsingOnline

Brief title
Vascular calcification, vitamin K, different phosphate binders and MGP

Condition

- Coronary artery disorders
- Nephropathies
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
vascular calcification atherosclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Alkmaar
Source(s) of monetary or material Support: nierstichting,Vrije Universiteit Medisch Centrum

Intervention

Keyword: MGP, phosphate binders, vascular calcification, vitamin K

Outcome measures

Primary outcome

Difference in dp-ucMGP en PIVKA-II levels after eight weeks of treatment with

lanthanumcarbonate or calciumcarbonate.

Secondary outcome

Difference in dp-ucMGP and PIVKA-II levels after menaquinon suppletion.

Study description

Background summary

Vascular calcification are a common problem within dialysis population and are associated with higher mortality risk. Fifty percent of dialysis patients eventually pass away due to vascular calcification. A lot of dialysis patients use vitamin K antagonist which promote vascular calcification. In this project we try to comprehend which factors play a role in this process.
New bio marker involved in vascular calcification is matrix *-carboxy-glutamatee(Gla) protein (MGP) will be measured when different phosphate binders are used and PIVKA-II will be measured to see if there is a vitamin K deficiency.
Hypothesis is that different phosphate binders bind vitamin K in a different way in the intestinal tract. MGP is a vitamin K dependant factor and therefore expectataion is that MGP expression will be variable with different phosphate binders.
MGP will be measured as unphosphorylated, uncarboxylated MGP (dp-ucMGP) which is a free fraction and higher in dialysis patients with vascular calcification.

Study objective

This research will have as aim to look at progression or decrease of vascular calcification in dialysis population with use of different phosphate binders. There is a possibility that differect phosphate binders bind vitamin K in a different way in intestinal tract and thereby cause different level of calcification.
Level of calcification will be measured by dp-ucMGP which is used as markers for vascular calcification. Because of the fact that ucMGP en dp-ucMGP are vitamin K dependant PIVKA-II will be measured as well.
Better insight in mechanisms of vascular calcification under different circumstance can lead to therapeutic options which inhibit calcification and benefit survival of dialysis patients.

Study design

Prospective open cohort study in which used phosphate binders (usually a combination of a few binders) will be replaced by calciumcarbonate or lanthanumcarbonate (Fosrenol®) monotherapy for eight weeks only in patients which don't use vitamin K antagonists.
Choice for calciumcarbonate 3 dd 1000 mg or lanthanumcarbonate 3 dd 1000 mg as initial therapy will be randomized. After eight weeks the first phosphate binder will be replaced by the other one for once again a period of eight weeks. After the initial 16 weeks a period of 4 weeks will follow with suppletion of menaquinon (vitamin K2).

Intervention

Randomization between calciumcarbonate and lanthanumcarbonate with collection of blood samples. Blood will be drawn from hemodialysis shunt or catheter. And after 16 weeks a period of four weeks supplementation of menaquinone once daily 360 micrograms with continuation of the last phosphate binder.

Study burden and risks

There is no risk in participation in this research blood sampels will be drawn frequently and medication will be adjusted.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Dialysis patients older than 18 years without the prospect of renal function recovery and life expectancy longer than six months.

Exclusion criteria

1 Use of vitamin K antagonists
2 Calcium under 2,1 or above 2,6 mmol/l
3 Pregnancy
4 Phosphate under 1,4 or above 2,2 mmol/l
5 Allergy or intolerance for study medication
6 PTH under 15 or above 65 pmol/l

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-11-2014
Enrollment:	16
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	calcichew
Generic name:	calcium carbonate
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	fosrenol
Generic name:	lanthanumcarbonate
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	28-04-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-11-2014
Application type:	First submission

Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-01-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-02-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-09-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-06-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-09-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-10-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-11-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26614
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2013-003949-41-NL
CCMO	NL36810.094.13
OMON	NL-OMON26614