Liposoluble vitamins in patients receiving long-term octreotide treatment

Published: 12-01-2009
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To determine the frequency and severity of liposoluble vitamin malabsorption side effects of long term octreotide treatment and/or small bowel resection

Ethical review	Approved WMO
Status	Pending
Health condition type	Vitamin related disorders
Study type	Observational non invasive

Summary

ID

NL-OMON32903

Source
ToetsingOnline

Brief title
Liposoluble vitamins during octreotide treatment

Condition

- Vitamin related disorders

Synonym
liposoluble vitamin deficiency, shortage of liposoluble vitamins

Research involving
Human

Sponsors and support

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

Intervention

Keyword: acromegaly, carcinoid tumor, liposoluble vitamins, octreotide

Outcome measures

Primary outcome

Patients will be investigated for vitamin-status by measuring liposoluble vitamins, relevant lipid components and relevant biochemical investigations to measure effects of possible vitamin deficiency, including calciumlevels, PTH and coagulation in blood

Secondary outcome

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Study description

Background summary

Long-term octreotide therapy is an important medical treatment to control symptoms of hypersecretion of biological active amines and peptides in a number of diseases, such as acromegaly or carcinoid tumours. Side effects of octreotide treatment are usually acceptable and often passing. Octreotdide is registered for clinical use since 1989, while the now commonly used long-acting form became available in 1997.
There is some evidence pointing towards a risk liposoluble vitamin deficiency in patients receiving long-term octreotide treatment. This is becoming clear only recently as there are now patients using this drug since it became available. Groups especially using octreotide are acormegaly patients and patients with carcinoid, who have as additional reason for vitamin deficiency the fact that often a part of the small bowel is resected. However, vitamin status is not routinely assessed in these patients, even though vitamin deficiency can seriously affect quality of life.

Study objective

To determine the frequency and severity of liposoluble vitamin malabsorption side effects of long term octreotide treatment and/or small bowel resection

Study design

This is a cross-sectional explorative cohort study in patients receiving

long-term octreotide treatment for acromegaly or a carcinoid tumour. Patients are eligible when they have used octreotide for at least 18 months. Patients must be 18 years or older and must be willing to give written informed consent This investigation will be done by blood analysis at one time point

Study burden and risks

The blood analysis will be performed during routine outpatient visits, when regular blood samples are drawn. No serious adverse events are linked to the described study procedures. With this study we hope to get insight into the frequency and severity of deficiency of liposoluble vitamins in patients receiving long-term octreotide therapy. This will contribute to the early recognition and suppletion of (sub)clinical deficiencies thus improving patient*s health.

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

octreotide-treatment longer than 18 months

Exclusion criteria

-

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2008
Enrollment:	80
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL25367.042.08