Liposoluble vitamins in patients receiving longterm treatment with octreotide.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24514

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Vetoplosbare vitamine deficientie, carcinoid tumor, acromegalie

Liposoluble vitamin deficiency, carcinoid tumour, acromegaly

Sponsors and support

Primary sponsor: prof. dr. EGE de Vries
Universitair Medisch Centrum Groningen
9700 RB Groningen
the Netherlands
Source(s) of monetary or material Support: prof. dr. EGE de Vries
Universitair Medisch Centrum Groningen
9700 RB Groningen
the Netherlands

Intervention

Outcome measures

Primary outcome

1. Liposoluble vitamins;

2. Relevant lipid components;

3. Relevant biochemical investigations to measure effects of possible vitamin deficiency, including calcium levels, PTH and coagulation.

Secondary outcome

N/A

Study description

Background summary

This is a cross-sectional explorative cohort study in patients receiving long-term octreotide treatment (longer than 18 months) for acromegaly or a carcinoid tumour. Patients will be investigated for vitamin-status at one time point. 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.

Single-center studie in Groningen, the Netherlands

Study objective

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 design

This investigation will be done by blood analysis at one time point.

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

No informed consent, age less then 18 years.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2009
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion

Date:	17-03-2009
Application type:	First submission

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
NTR-new	NL1633

Register	ID
NTR-old	NTR1730
Other	MEC Groningen : 2008/286
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A