

# Liposoluble vitamins in patients receiving longterm treatment with octreotide.

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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...

|                             |                                                     |
|-----------------------------|-----------------------------------------------------|
| <b>Ethische beoordeling</b> | Positief advies                                     |
| <b>Status</b>               | Werving gestart                                     |
| <b>Type aandoening</b>      | -                                                   |
| <b>Onderzoekstype</b>       | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON24514

### Bron

Nationaal Trial Register

### Verkorte titel

N/A

### Aandoening

Vetoplosbare vitamine deficiëntie, carcinoid tumor, acromegalie

Liposoluble vitamin deficiency, carcinoid tumour, acromegaly

## Ondersteuning

**Primaire sponsor:** prof. dr. EGE de Vries

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**Overige ondersteuning:** prof. dr. EGE de Vries

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## Onderzoeksproduct en/of interventie

### Uitkomstmaten

#### Primaire uitkomstmaten

1. Liposoluble vitamins;<br>
2. Relevant lipid components;<br>
3. Relevant biochemical investigations to measure effects of possible vitamin deficiency, including calcium levels, PTH and coagulation.

## Toelichting onderzoek

### Achtergrond van het onderzoek

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

### Doel van het onderzoek

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 acromegaly 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.

### Onderzoeksopzet

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

### Onderzoeksproduct en/of interventie

N/A

## Contactpersonen

### Publiek

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### Wetenschappelijk

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

No informed consent, age less than 18 years.

## Onderzoeksopzet

## Opzet

|                  |                                                     |
|------------------|-----------------------------------------------------|
| Type:            | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Anders                                              |
| Toewijzing:      | N.v.t. / één studie arm                             |
| Blinding:        | Open / niet geblindeerd                             |
| Controle:        | N.v.t. / onbekend                                   |

## Deelname

|                         |                      |
|-------------------------|----------------------|
| Nederland               |                      |
| Status:                 | Werving gestart      |
| (Verwachte) startdatum: | 01-01-2009           |
| Aantal proefpersonen:   | 80                   |
| Type:                   | Verwachte startdatum |

## Ethische beoordeling

|                 |                  |
|-----------------|------------------|
| Positief advies |                  |
| Datum:          | 17-03-2009       |
| Soort:          | Eerste indiening |

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

| Register | ID     |
|----------|--------|
| NTR-new  | NL1633 |

**Register**

NTR-old

Ander register

ISRCTN

**ID**

NTR1730

MEC Groningen : 2008/286

ISRCTN wordt niet meer aangevraagd

## Resultaten

**Samenvatting resultaten**

N/A