# Is treatment with octreotide effective in patients with head-and-neck paraganglioma?

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Evaluation of the effects of octreotide LAR in head-and-neck paraganglioma on:1. tumor volume 2. catecholamine produktion 3. clinical and biochemical parameters

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Endocrine neoplasms benign |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON30072

**Source**
ToetsingOnline

**Brief title**
octreotide in head and neck paraganglioma

### Condition

- Endocrine neoplasms benign

**Synonym**
glomustumor, paraganglioma

**Research involving**
Human

### Sponsors and support

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

## Intervention

**Keyword:** head-and-neck region, octreotide, paraganglioma

## Outcome measures

### Primary outcome

1. tumorvolume

2. catecholamine produktion

### Secondary outcome

clinical and biochemical parameters (symptoms, related to the head-and-neck

paraganglioma and/or additional catecholamine production, blood pressure and

pulse rate, 24 hour blood pressure)

# Study description

### Background summary

Paraganglioma/glomustumors of the head-and-neck aerea usually grow slowly. Because of their slow growth velocity, their location in the near presence of vital structures (large vessels, nerves) and the fact that surgical resection is frequently complicated by gross morbidity and sometimes mortality, the current strategy is to wait-and-scan, using MRI-scanning to follow growth potency. In case of fast growth (>/ 20%/year), locally agressive behaviour or local complications, surgical treatment follows. Extension of the therapeutic arsenal with tumor volume reductive therapy is strongly needed. Sometimes, head-and-neck paraganglioma also produce catecholamines. Head-and-neck paraganglioma, that express the somatostatin-2 receptor, can usually be made visible by somatostatin receptor scintigraphy, which is positive in ~94% of cases. Frequenly, somatostatin receptor scintigraphy is used to visualize multifocal presence of head-and-neck paraganglioma.
Somatostatin analogues, that bind to somatostatin receptors, are used for many years in the treatment of neuro-endocrine tumors. Both in vitro and in vivo antiproliferative effects of somatostatin analogues are described. The effects are both cytostatic and cytotoxic of nature. Cytostatic effects are brought about by 4 of 5 somatostatin receptors (sst 1,2,4,5), cytotoxic effects by sst3. As a result of these effects, somatostatin analogues can reduce tumor volume and additional hormone production in patients with GH-secernating

pituitary tumors and other neuro-endocrine tumors like carcinoids and gastrinomas.
Aim of the present study is to evaluate the efficacy of longacting somatostatin (OCT-LAR) on tumor volume and/or additional catecholamine overproduction by head of head-and-neck paraganglioma.

## Study objective

Evaluation of the effects of octreotide LAR in head-and-neck paraganglioma on:
1. tumor volume
2. catecholamine produktion
3. clinical and biochemical parameters

## Study design

30 patients with somatostatinscan positive head-and-neck paraganglioma will be included in the study, with tumors that grow fast (>/ 20%/year) and/or are complicated by recent cranial nerve palsy (< 1 year ago) and/or catecholamine overproduction. Patients will be tested before and after 12 months of treatment with longacting somatostatin (OCT-LAR). Patients with catecholamine overproduction by the head-and-neck paraganglioma will get an intravenous octreotide test as well, versus a controltest using saline, 1 and 2 weeks before starting OCT-LAR (random 50% of patients start with octreotide 50 microgram iv, after which a wash-out period of 1 week follows, followed by repeating the test with saline iv, and vice versa).

A prospective intervention study design has been chosen, in which each patient is her/her own control. The study is not-placebo-controlled, not blinded, since (in general small) side effects can be expected which will make the nature of what has been administrated clear for both the patient and the researcher. In addition, outcome parameters can be measured objectively.

## Intervention

Treatment with long-acting somatostatin (Sandostatin LAR) with monthly intramuscular injections with a dose of 30 mg during 1 year.

## Study burden and risks

The reseach protocol consists of the following evaluations before and after 6 and 12 month's of the start of the treatment with octreotide LAR: (see also flow-sheet page 15)
-glomus-related complaints, blood pressure and pulse rate
-blood analysis; ~300 cc blood will be taken during the total study
-urine analysis: patients will be asked to collect 48-hour urine, 5x in case of no-hormone producing tumor, 9x in case the head-and-neck paraganglioma produces

catecholamines
-before the start of the stduy, and at the end of the study, an abdominal ultrasound will be performed: in case of the presence of cholelithiasis before the start of the study, patients will be excluded
-if no octreotide scan has already been performed, this scan will be performed before the start of the study
-before the start of the study and after 12 months, an MRI of the head-and-neck region will be performed, in addition to a 24 hour blood pressure registration
-in case of a catecholamine producing head-and-neck paraganglioma, an intravenous octreotide test versus a saline test will be performed 1 and 2 weeks before starting treatment with octreotide LAR (with 1 week wash-out time in between tests), during which blood will be sampled during 2 hours at different time points to measure catecholamine concentrations. In addition, from 2 days preceeding the test and 2 days after the test, urine will be collected for the measurement of these hormones.
Octreotide has potential side effects: these are pain, redness and soreness of the site of injection, and gastrointestinal side effects as anorexia, nausea, vomiting, flatulence, abdominal cramps, and diarrea. In addition, cholelithiasis can be aggravated, and be induced, especially during longer treatment, and glucose intolerance can be induced. Sporadically, hear loss, acute pancreatitis and acute hepatitis can be induced.

patients will be selected on the basis of a positive octreotide scan, which is routinely performed in this patient group to evaluate location, multifocal presence and extension of the head-and-neck paraganglioma. For our research protocol, therfore, already performed octreotide scans will be used to prevent unnecessary radiation exposure for patients.

## 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

-presence of one or more head-and-neck paraganglioma that grow fast (>/ 20%/year) and/or are complicated by recent cranial nerve palsy (<1 year ago)and/or production of catecholamines
-age 18-75 years
-positieve octreotidescan
-informed consent

## Exclusion criteria

-necessity for surgical resection of the head-and-neck paraganglioma
-presence of additional paraganglioma in the thorax or abdomen
-presence of metastases of the head-and-neck paraganglioma
-cholelithiasis
-diabetes mellitus
-severe renal insufficiency (creatinine > 150 micromol/L), or liver failure(ALAt and/or ASAT increased >3x)
-recent participation in other research projects (< 3 month's ago), or participation in >2 projects the past year
-(wish for) pregnancy
-presence of an adrenal tumor, suspect for phaeochromocytoma. These patients will be operated (adrenalectomy) first. In all other patients who participate, an MIBG scan and an MRI svan will be performed in case of overproduction of catecholamines

# Study design

## Design

**Study type:** Interventional

| | |
|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 16-09-2009 |
| Enrollment: | 30 |
| Type: | Actual |

## Medical products/devices used

| | |
|---|---|
| Product type: | Medicine |
| Brand name: | Sandostatine LAR |
| Generic name: | Octreotide long-acting release |
| Registration: | Yes - NL outside intended use |

# Ethics review

Approved WMO

| | |
|---|---|
| Date: | 23-10-2006 |
| Application type: | First submission |
| Review commission: | METC Leids Universitair Medisch Centrum (Leiden) |

# 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 | EUCTR2006-002603-13-NL |
| CCMO | NL12417.058.06 |

# Study results

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|---|---|
| Date completed: | 19-10-2012 |
| Results posted: | 15-11-2022 |
| Actual enrolment: | 4 |

**Summary results**
Trial ended prematurely

**First publication**
15-11-2022