# Efficacy and safety of treatment with Cinacalcet in patients with Primary Hyperparathyroidism due to a MEN-1 mutation

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1. What are the effects of cinacalcet on clinical and biochemical parameters, including bone turnover markers, in patients with primary hyperparathyroidism due to a MEN-I mutation?2. What are the effects of cinacalcet on bone mineral density and…

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Chromosomal abnormalities, gene alterations and gene variants |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON34871

**Source**
ToetsingOnline

**Brief title**
Cinacalcet in MEN-I PHPT

### Condition

- Chromosomal abnormalities, gene alterations and gene variants
- Parathyroid gland disorders

**Synonym**
hyperactive parathyroid glands, primary hyperparathyroidism

**Research involving**
Human

## Sponsors and support

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

## Intervention

**Keyword:** Cinacalcet, MEN-1 mutation, Primary hyperparathyroidism

## Outcome measures

### Primary outcome

1. Clinical parameters

2. Biochemical parameters

3. Radiological parameters; MRI-abdomen, MRI- pituitary, bone mineral density,

ultrasound of kidney, X-spine

4. Safety parameters

### Secondary outcome

CaSR expression analysis on available pathological specimens

# Study description

### Background summary

Primary hyperparathyroidism (PHPT) is the most common cause of hypercalcaemia in the population. Less than 5% of the patients with PHPT has a hereditary mutation, such as the MEN-I en MEN-IIa syndrome. More than 95% of the patients with a MEN-I syndrome, however, develop PHPT, 50% develops a pituitary adenoma and 33% develops a insulinoma, gastrinoma, or other pancreas tumor. Patients with PHPT can only be definitively cured by surgical excision of all pathological parathyroid glands. Recently it has been proven that calcimimetics, such as cinacalcet (Primpara ®), can sensitize the calcium-sensing receptor (CaSR) for extracellulair calcium, and decrease the serum calcium and PTH concentrations. At the moment cinacalcet is the only calcimimetic that is approved for the treatment of patients with PHPT. The CaSR is located on the parathyroid cells, but also on the cells of the kidney, bones, intestine, thyroid, brain, pancreas and gastrinoma cells of the stomach.

Therefore, it could be possible that cinacalcet does not only influence the CaSR on the parathyroidcells, but also on the other organs, however this has not yet been properly studied. Therefore, the aim of our study is to evaluate the efficacy and safety of treatment with cinacalcet in patients with PHPT due a MEN-I mutation.

### Study objective

1. What are the effects of cinacalcet on clinical and biochemical parameters, including bone turnover markers, in patients with primary hyperparathyroidism due to a MEN-I mutation?
2. What are the effects of cinacalcet on bone mineral density and nefrolithiasis in patients with primary hyperparathyroidism due to a MEN-I mutation?
3. What is the effect of cinacalcet on the development and/or growth of pituitary adenomas, insulinomas, gastrinomas and/or other pancreatic tumors in patients with primary hyperparathyroidism due to a MEN-I mutation?
4. Is there a loss or decrease of the CaR expression in pathological specimens obtained at surgery in patients with primary hyperparathyroidism due to a MEN-I mutation? And does this influence the response to treatment with cinacalcet?

### Study design

One year single-centre, prospective intervention study

### Intervention

Treatment with cinacalcet (Mimpara) 30 mg twice daily for a duration of 1 year.

### Study burden and risks

Patients will undergo the standard biochemical and radiological work-up necessary for the evaluation of MEN-1 associated disorders and complications of primary hyperparathyrodism.
They will also undergo a neuropsycological examination to evaluate the presence of alteration in cognitive function during treatment with cinacalcet.

## 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

Primary hyperparathyroidism due to a genetically confirmed MEN-1 mutation

## Exclusion criteria

No MEN-1 mutation

# Study design

## Design

| | |
|---|---|
| Study phase: | 4 |
| Study type: | Interventional |
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |

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|---|---|
| Primary purpose: | Treatment |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 26-07-2010 |
| Enrollment: | 20 |
| Type: | Actual |

### Medical products/devices used

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|---|---|
| Product type: | Medicine |
| Brand name: | Mimpara |
| Generic name: | Cinacalcet |
| Registration: | Yes - NL intended use |

## Ethics review

Approved WMO

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|---|---|
| Date: | 23-04-2010 |
| Application type: | First submission |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>metc-ldd@lumc.nl |

## 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 | EUCTR2010-018861-53-NL |
| CCMO | NL30971.058.10 |