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…

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

Primary purpose:	Treatment

Recruitment

NL

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

Medical products/devices used

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

Ethics review

Approved WMO

Date:	23-04-2010
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) 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