EValuation Of Cinacalcet HCL Therapy to Lower CardioVascular Events

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Secondary HPT is common in people with CKD. Patients with secondary HPT often have high PTH levels and may develop large parathyroid glands in the neck. Patients with secondary HPT may have bone disease (osteodystrophy). This bone disease may cause...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON30733

Source
ToetsingOnline

Brief title
EVOLVE

Condition

- Other condition
- Heart failures
- Nephropathies

Synonym
mortality and cardiovasculair morbidity

Health condition

overlijden (door welke oorzaak dan ook)

Research involving
Human

Sponsors and support

Primary sponsor: Amgen
Source(s) of monetary or material Support: Amgen financiert het onderzoek

Intervention

Keyword: 4 years, Cardiovasculair events, Cinacalcet, Phase 3 trial

Outcome measures

Primary outcome

Time to the composite event comprising all-cause mortality or non-fatal cardiovascular events (MI, hospitalization for unstable angina, HF, or peripheral vascular event)

Secondary outcome

• Time to all-cause mortality

• Time to cardiovascular mortality

• Time to fatal and non-fatal MI

• Time to fatal and non-fatal hospitalization for unstable angina

• Time to fatal and non-fatal HF event

• Time to fatal and non-fatal peripheral vascular event

• Time to fatal and non-fatal stroke

• Time to bone fracture

• Time to parathyroidectomy

Study description

Background summary

In this study, the study medication cinacalcet is evaluated for the treatment

of patients with CKD with secondary HPT on dialysis. This study will include a total of approximately 3800 subjects from approximately 500 centers in North, Central and South America; Australia; and Europe. Amgen Inc. (hereafter known as *Amgen*), a for-profit drug company, is sponsoring and funding this clinical study. The investigational product being tested in this research study is called cinacalcet. Cinacalcet acts directly on the calcium-sensing receptors on the surface of the parathyroid gland cells to increase the parathyroid glands sensitivity to calcium levels. The European Committee for Medicinal Products for Human Use (CHMP) has approved cinacalcet (Mimpara®; Parareg®) for the treatment of secondary HPT in patients with CKD on dialysis as well as for the treatment of hypercalcemia (high calcium) in patients with parathyroid carcinoma (a cancer of the parathyroid gland).

Study objective

Secondary HPT is common in people with CKD. Patients with secondary HPT often have high PTH levels and may develop large parathyroid glands in the neck. Patients with secondary HPT may have bone disease (osteodystrophy). This bone disease may cause bone pain, fractures, and poor formation of red blood cells. Other problems from secondary HPT may include increases in blood levels of calcium and phosphorus. These may cause calcium to deposit in body tissues. Calcium deposits can cause arthritis (joint pain and swelling), muscle inflammation, itching, gangrene (death of soft tissue), or heart and lung problems. New evidence suggests that secondary HPT is associated with cardiovascular disease and increased death risk. The purpose of this study is to evaluate the effects of cinacalcet (or Mimpara®) on cardiovascular events and death in chronic kidney disease patients with secondary HPT who are receiving dialysis.

Study design

This is a multicentre, randomized, double-blind, phase 3 study. The study will consist of a 30-day screening period followed by 2 consecutive phases (periods): a dose-titration period (in this phase, your best dose is determined) lasting 20 weeks with study visits every 2 weeks and a follow up period with study visits every 8 weeks that will last approximately 4 years or until Amgen notifies the sites that the study has been completed or terminated. Subjects who qualify for the study will be randomized at a 1:1 ratio to the following groups:
Group A: Cinacalcet (active)
Group B: Placebo (control group)
The inclusionperiod is from September 2006 till January 2008.

Intervention

Cinacalcet is taken orally every day. The passible dose is cinacalcet or

placebo 30, 60, 90, 120 en 180 mg.

Study burden and risks

The total trial duration is expected to be approximately 4 years. The study duration of an individual subject will depend on when the subject starts the study: It is expected that the first subject enrolled into this study will be followed for approximately 4 years and the last subject enrolled will be followed for approximately 2.5 years. In these 4 years the patient will have approximately 35 study visits, these visits will be planned (if possible) with the patients regular dialysis visits. In general the visits consist of reporting adverse events, concomitant medication, blood samples are taken for various laboratory measurements and cinacalcet/placebo will be dispensed.

The most common side effects in subjects receiving cinacalcet were, nausea and vomiting. In general, the episodes of nausea and vomiting did not require treatment and subjects were able to complete the study.
One of the expected actions of cinacalcet is to reduce blood calcium levels. Blood calcium levels will be monitored and appropriate action(s) will be taken as necessary. Cinacalcet may affect the body*s ability to remove certain medications. In addition, certain medications may affect the body*s ability to remove cinacalcet. Therefore, the study doctor may need to adjust the dose of medications. Patients will be monitored closely to minimize the risk of any side effects.

Contacts

Public
Amgen

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NL
Scientific
Amgen

Minervum 7061
4800 DH Breda
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

>= 18 years of age
treated with maintenance hemodialysis 3 times a week for >= 3 months before randomization
PTH >= 31.8 mmol/L
Ca >= 2.1 mmol/L
Ca x P >= 3.63 mmol/L

Exclusion criteria

Parathyroidectomy in the 12 weeks prior to randomization
received therapy with cinacalcet within 3 months of randomization
Hospitalization within 12 weeks of randomization for any of the following events:
a. MI
b. Unstable angina
c. HF
d. Peripheral vascular disease
e. Stroke
History of seizure within 12 weeks prior to randomization
Scheduled date for kidney transplant from a known living donor
Anticipated parathyroidectomy within 6 months after randomization.

Study design

Design

Study phase:	3
Study type:	Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-01-2007
Enrollment:	56
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:	04-07-2006
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-09-2006
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	31-10-2006
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	16-11-2006
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-12-2006
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	02-01-2007
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	09-01-2007
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-02-2007
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-03-2007
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	02-04-2007
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-04-2007
Application type:	Amendment

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-05-2007
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-05-2007
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-05-2007
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-10-2007
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-12-2007
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-08-2008
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-08-2008
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	24-08-2009
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	31-08-2009
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	16-09-2009
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	11-11-2009
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Not approved

Date:	12-11-2009
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	22-06-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	17-08-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	24-08-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United

	(Nieuwegein)
Approved WMO Date:	10-09-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	14-10-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-10-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	18-11-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-11-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-07-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	EUCTR2006-002075-40-NL
CCMO	NL13189.100.06