

The validation and implementation of the Dutch version of the Quality of Life questionnaire for patients with primary hyperparathyroidism (PHPQoL)

Published: 11-05-2017

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Primary objective: To validate a disease-specific HRQoL questionnaire i.e., the PHPQoL, in a Dutch cohort. Secondary objective: To determine the effect of surgery, medical treatment or conservative treatment in patients with PHPT within our CCT.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Parathyroid gland disorders
Study type	Observational non invasive

Summary

ID

NL-OMON50339

Source

ToetsingOnline

Brief title

Validation and implementation of the Dutch version of the PHPQoL

Condition

- Parathyroid gland disorders

Synonym

Hyperparathyroidism

Research involving

Human

Sponsors and support

Primary sponsor: Endocrinologie

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Disease specific, Hyperparathyroidism, Quality of Life

Outcome measures

Primary outcome

QoL

Secondary outcome

nvt

Study description

Background summary

Primary hyperparathyroidism (PHPT) is an endocrine disease characterized by elevated levels of parathyroid hormone (PTH) most of the time caused by a parathyroid tumor or hyperplasia. As a result of the hyperparathyroidism, patients are exposed to increased calcium levels. Poor control of hypercalcemia can increase the risk of mortality, due to its negative effect on the cardiovascular-, gastrointestinal-, and nervous system, as well as on the kidneys, bones and muscles. However, most patients with hyperparathyroidism remain asymptomatic with calcium levels <2.9 mmol/L and absence of kidney or bone disorders. Currently these patients are not treated with surgery, since strict criteria for surgery are maintained including calcium levels >2.9 mmol/L, presence of renal stones and osteoporosis.

Besides physical symptoms, PHPT has been associated with psychopathology, neuropsychological problems and impairments in health-related quality of life (HRQoL), which significantly improves after surgical treatment. However, the benefit of surgery in terms of improving HRQoL in asymptomatic patients or in patients with minor symptoms remains inconclusive.

For the assessment of HRQoL it is usually recommended to use both a generic questionnaire and a disease-specific questionnaire, in order to examine general aspects of HRQoL, as well as specific HRQoL aspects relevant for a particular disease]. Adequate assessment of HRQoL is important for the evaluation of treatment and individual treatment choices in patient care. HRQoL assessment is also used in clinical trials or to evaluate HRQoL in patient populations [9].

Recently, a disease-specific HRQoL questionnaire for PHPT has been developed and validated i.e., the PHPQoL]. Currently, this questionnaire is only

available in Spanish and English. The aim of the present research protocol is to translate the PHPQoL into Dutch, and validate it in a Dutch cohort of patients with PHPT. When the Dutch PHPQoL is found to be valid and reliable, it will be used as a standard quality check in our coordinated care trajectory (CCT) HPT. The availability of a Dutch version of the PHPQoL will optimize treatment for patients with (a) symptomatic PHPT.

Study objective

Primary objective: To validate a disease-specific HRQoL questionnaire i.e., the PHPQoL, in a Dutch cohort.

Secondary objective: To determine the effect of surgery, medical treatment or conservative treatment in patients with PHPT within our CCT.

Study design

A prospective cohort study including consecutive patients of the CCT PHPT. Translation of the PHPQoL will be performed according to international standards by using the forward-backward method and debriefing interviews with patients.

Patients visiting the outpatient clinic of the department of Endocrinology and Endocrine Surgery will be invited to fill out the Dutch PHPQoL and two other HRQoL measures (i.e., SF-36, EQ-5D) at time of diagnosis and 3 months after treatment or in case of conservative treatment at the first follow-up visit.

Study burden and risks

The PHPQoL is a 16-item questionnaire containing disease-specific HRQoL items. The other generic HRQoL questionnaires (i.e., SF-6D, EQ-5D) consist of 6 items and 5 items respectively. We consider the patient perceived burden minimal.

Contacts

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Age > 18 years and a diagnosis of Primary Hyperparathyroidism willing to participate.

Exclusion criteria

Inability to fill out the questionnaire

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated):	11-10-2017
Enrollment:	88
Type:	Actual

Ethics review

Approved WMO	
Date:	11-05-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO	
Date:	23-08-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO	
Date:	10-08-2020
Application type:	Amendment
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

CCMO

ID

NL60320.058.17

Study results

Date completed: 05-12-2022

Actual enrolment: 89

Summary results

Trial is ongoing in other countries