Value Based Healthcare and the Expectations and Experiences in Pituitary Tumor Treatment

Published: 05-07-2016
Last updated: 16-04-2024

To describe the treatment expectations of patients with a pituitary tumor undergoing treatment as well as patients' evaluation of the perioperative trajectory. Moreover, we will determine the fulfilment of expectations and clinical outcomes...

Ethical review	Approved WMO
Status	Pending
Health condition type	Hypothalamus and pituitary gland disorders
Study type	Observational non invasive

Summary

ID

NL-OMON43186

Source
ToetsingOnline

Brief title
VAPIT

Condition

- Hypothalamus and pituitary gland disorders
- Nervous system, skull and spine therapeutic procedures

Synonym
hypophysis tumors, Pituitary tumors

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: Expectations, Pituitary, Surgery, VBHC

Outcome measures

Primary outcome

Patients' expectations and the fulfillment of these expectations

Secondary outcome

Quality of life

Study description

Background summary

Pituitary tumors occur in an estimated 2,0/100.000 persons per year16 and can lead to a substantial decrease in quality of life.8-15 Depending on the tumor type, size and complaints a tumor can either be surgically resected or medically treated. Results from the Leiden University Medical Center (LUMC) have shown that a biochemical remission can be achieved in 66% and 72% of the Acromegaly and Cushing patients. Visual improvement was seen in 82% of the Non-functioning macroadenomas after surgery17 and a curation rate of 67% has been achieved in intolerant/resistant Prolactinoma patients at 6 months after surgery.30 So far, knowledge on patient expectations of treatment is scarce.

Study objective

To describe the treatment expectations of patients with a pituitary tumor undergoing treatment as well as patients' evaluation of the perioperative trajectory. Moreover, we will determine the fulfilment of expectations and clinical outcomes until 6 months after treatment.

Study design

Observational, longitudinal and monocenter design

Study burden and risks

There is no additional risk involved considering the observational nature of the study. The only possible burden patients could experience is the additional

time it costs them. They will be asked to fill out questionnaires, which will be assessed around their standard care. It takes approximately 45 minutes to fill out the forms.

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

- All patients with a pituitary tumor who are scheduled for primary or revision pituitary tumor surgery
- All pituitary patients with a pituitary tumor who will receive new medication for the treatment of his/her pituitary tumor
- All patients with a pituitary tumor who will undergo radiotherapy for the treatment of his/her pituitary tumor
- Patients > 18 years of age

- Signed informed consent

Exclusion criteria

- Insufficient knowledge of the Dutch language
- Physical or mental conditions interfering with the understanding and completion of questionnaires
- Signed informed consent

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	14-05-2016
Enrollment:	150
Type:	Anticipated

Ethics review

Approved WMO

Date:	05-07-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	21-09-2016

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	ID
CCMO	NL57212.058.16