Identification of the posterior lobe of the human pituitary gland during surgery using its electrophysiological, neural signature

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To record and analyse the electrophysiological properties and differences of the human pituitary gland, i.e. the anterior lobe, posterior lobe and adenoma.

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

Summary

ID

NL-OMON55741

Source
ToetsingOnline

Brief title
Typing the electrophysiology of the human pituitary gland

Condition

- Hypothalamus and pituitary gland disorders

Synonym
pituitary adenoma, pituitary tumor

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Medtronic B.V.

Intervention

Keyword: Diabetes insipidus, Electrophysiology, Pituitary gland

Outcome measures

Primary outcome

Electrophysiological characteristics of different pituitary regions, i.e.

firing patterns, voltages and frequency of spontaneous discharges. The

following areas of the pituitary gland are of interest to us: the posterior

pituitary lobe, central and lateral part of the anterior pituitary lobe,

pituitary adenoma.

Secondary outcome

Durantion, outcome and complications of surgery

Study description

Background summary

Pituitary surgery is performed to remove adenomas. During pituitary surgery, differentiating between anterior lobe, posterior lobe, and adenoma can be very challenging, but extremely important because of the need for preservation of the normal gland tissue and complete removal of the adenoma. In current surgical technique only tissue consistency and colour are used to discriminate, for which small incisions in, and manipulation of, the pituitary gland are needed.
In the current study protocol we want to investigate if we can use the electrophysiological properties of the posterior lobe, which consists of neural axons from the hypothalamus, to reliably identify it. Electrical measurements are done with microelectrodes, which are routinely used in clinical practice for Deep Brain Stimulation (DBS). The electrical measurement is significantly less traumatic than current surgical manipulation to inspect the gland. We therefore expect that introduction of this technique will reduce the complication rate of pituitary surgery, particularly the rate of diabetes insipidus. Because pituitary cells of the anterior lobe also show electrical activity, with different characteristics for each cell type, recording of the

electrical signature may also help with identification of adenoma tissue.

Study objective

To record and analyse the electrophysiological properties and differences of the human pituitary gland, i.e. the anterior lobe, posterior lobe and adenoma.

Study design

Observational, exploratory study

Study burden and risks

Use of the microTargeting electrodes is routine clinical practice in DBS surgery. The overall risk of haemorrhage in DBS is 0-8%, most often reported as 1-2%. These haemorrhages are most often clinically not significant or cause only temporary neurological deficits. In our study the electrode will be placed directly into the pituitary tissue, without passing any brain tissue, therefore the risk of a brain haemorrhage is zero. The risk of insertion only one microelectrode is unknown, but will be lower because it is thinner than the final DBS lead. When the risk of a pituitary haemorrhage is estimated to 2%, this is significantly lower than the risk of tissue damage through surgical manipulation. In our current series, postoperative diabetes insipidus, caused by damage of the posterior lobe, occurs 20% temporary and 5% permanently. We expect that already in the study population this incidence will be reduced because of early and less traumatic identification of the posterior lobe.

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

- Male and female patients undergoing transsphenoidal surgery for pituitary adenoma.
- Identification of the posterior lobe on pre-operative MRI. This is most common in patients with microadenomas or small macroadenomas.
- Age >18 years

Exclusion criteria

- Emergency surgery
- Cognitive impairments
- Pregnancy
- Pre-existing diabetes insipidus

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-12-2020
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	microelectrode
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	12-08-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	01-03-2021
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	NL69304.058.19