A method for non-invasive intracranial pressure measurement in glaucoma

Published: 17-03-2017
Last updated: 11-04-2024

Primary Objective: The primary objective is to evaluate the use of DPOAEs as a representation of ICP in Glaucoma patients by investigating changes in DPOAE amplitudes and phase angles with changes in posture in subgroups of glaucoma patients and in...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glaucoma and ocular hypertension
Study type	Observational non invasive

Summary

ID

NL-OMON45351

Source
ToetsingOnline

Brief title
Non-invasive ICP Measurement in Glaucoma

Condition

- Glaucoma and ocular hypertension

Synonym
Glaucoma; POAG

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,European committee and Uitzicht

Intervention

Keyword: Distortion Product Otoacoustic Emissions, Glaucoma, Intracranial Pressure, Non-invasive

Outcome measures

Primary outcome

Amplitudes and phase angles of DPOAEs as a function of posture for different

subgroups of Glaucoma and healthy controls. Blood pressure, corneal thickness,

and systemic medication will be recorded as well, being possible confounders.

Secondary outcome

N/A

Study description

Background summary

Glaucoma is a chronic, progressive disease of the optic nerve in which there are detrimental effects on field of vision and visual acuity. The relationship between intraocular pressure (IOP) and intracranial pressure (ICP) is a crucial aspect of the pathology of Glaucoma. At the back of the eye is a mesh-like structure called the lamina cribrosa (LC) that contains pores through which the optic nerve fibers run. Alterations in IOP, ICP, or both can lead to a change in the pressure gradient across the LC and cause it to bulge and damage the nerve fibers. If left untreated, this can eventually lead to blindness.

Currently the only clinically reliable methods of measuring ICP are by lumbar puncture and intraventricular catheter, two extremely invasive techniques. It is therefore necessary to establish an accurate non-invasive measurement of ICP for evaluating the cause and progression of Glaucoma. Distortion product otoacoustic emissions (DPOAEs) may be one such method.

DPOAEs are sounds emitted by the inner ear in response to tones at specified levels and frequencies that are presented by a microphone placed in the ear. These emissions are thought to represent ICP because there is a connection between the cranium and perilymphatic fluid via the cochlear aqueduct. Previous research has shown that DPOAEs can accurately represent changes in ICP.

The proposed study investigates the utility of DPOAEs to represent changes in ICP in healthy controls and in 3 patient populations. The first patient group will have diagnosed glaucoma and raised IOP and the second will have diagnosed glaucoma but normal IOP (this is called normal tension glaucoma, or NTG). Finally, there is patient population that has raised IOP, but does not have any signs of glaucoma. It is suspected that these patients enjoy a compensatory rise in ICP that protects the LC. This will be our third patient group.

To the best of our knowledge, this technique has never been utilized to measure ICP in glaucoma patients. It has been shown with invasive techniques that patients with glaucoma have a lower ICP than the healthy population and that those with NTG have the lowest. We aim to reproduce these findings with a noninvasive measurement.

Study objective

Primary Objective:
The primary objective is to evaluate the use of DPOAEs as a representation of ICP in Glaucoma patients by investigating changes in DPOAE amplitudes and phase angles with changes in posture in subgroups of glaucoma patients and in healthy controls. Blood pressure, corneal thickness, and systemic medication will be recorded as well, being possible confounders.

Hypothesis 1:
The changes in DPOAEs from upright to 30 degrees HDT will be greatest for subjects who are expected to have the lowest ICP (primarily NTG subjects). Alternatively, the least amount of change in DPOAEs will occur in subjects who are expected to have the highest ICP (primarily the high IOP, non glaucomatous subjects).

Hypothesis 2:
Those with the greatest difference between IOP and ICP will have the most severe disease progression.

Study design

Cross-sectional, observational study

Study burden and risks

Patients and healthy subjects will have one visit to the ENT and ophthalmology departments to perform the screening tests and if selected, the experiment. Healthy subjects will undergo a routine screening test in the ophthalmology department to rule out the presence of glaucoma. Screening in the ENT department will take place for patients and healthy subjects and will include tympanometry to assess any middle ear problems, audiograms to determine hearing

threshold, and a test to detect the presence or absence of DPOAEs. If abnormal eye screening results are obtained for healthy subjects, they will be referred to their GP, as will be the case for ear abnormalities in all participants. Detection of signs of an eye or ear condition may cause psychological stress, however, an early diagnosis will allow treatments to be initiated and therefore more preservation of visual or hearing functioning. Glaucoma patients will not perform any ophthalmological screening tests; therefore there is no risk of identifying any other eye conditions. Subjects who meet the selection criteria will then undergo the DPOAE testing. The test is non-invasive but they will be tilted on a table, which may cause minimal discomfort. Patients will spend 1 hour for reception, additional questions, and screening and, if they meet the selection criteria, 40 minutes for the experiment. The total time will therefore be about 1 hour and 40 minutes. Healthy subjects will require 30 extra minutes for the eye screening, which will make their total participation time 2 hours and 10 minutes.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9713 GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

50-70 years of age
Presence of DPOAEs in one ear
For healthy controls: Upright IOP of 21mmHg or lower
For high pressure glaucoma: Diagnosed Glaucoma, upright IOP over 21mmHg before the onset of IOP lowering treatment, and established disease progression rate based on perimetry
For normal tension glaucoma: Diagnosed Glaucoma, upright IOP of 21mmHg or lower with or without IOP lowering treatment, and established disease progression rate based on perimetry
For high IOP with no glaucoma: Upright IOP of 22mmHg or higher
Written informed consent.

Exclusion criteria

No presence of DPOAEs
For healthy controls, any eye disease or family history of glaucoma

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-05-2017
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	17-03-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL59638.042.16
Other	UMCG Register and NTR