

# The ocular Vestibular Evoked Myogenic Potentials (oVEMPs) in patients with BRIC type 1 disease

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To gain information about the characteristics of the oVEMP response in patients with BRIC type 1

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Inner ear and VIIIth cranial nerve disorders
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON33203

### Source

ToetsingOnline

### Brief title

oVEMP test in BRIC type 1 disease

### Condition

- Inner ear and VIIIth cranial nerve disorders

### Synonym

BRIC type 1, dizziness, vertigo

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht

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

## Intervention

**Keyword:** BRIC type 1, diagnostics, otolith organs, oVEMP

## Outcome measures

### Primary outcome

The main study parameters are the amplitude and the threshold of the oVEMP response.

### Secondary outcome

Other characteristics of the oVEMP-response, such as the latencies of the various peaks in the response. All variables will be studied in relation to the level of the oVEMP-evoking sound stimulus.

## Study description

### Background summary

Familial intrahepatic cholestasis type 1 (FIC1) disease is an autosomal recessive disease caused by mutations in the ATP8B1-gene, which presents with intrahepatic cholestasis either as benign recurrent intrahepatic cholestasis type 1 (BRIC type 1) or progressive intrahepatic cholestasis type 1 (PFIC type 1). In addition, some patients develop extrahepatic symptoms, such as pancreatitis, diarrhoea, growth retardation and perceptive hearing loss, associated with degeneration of the cochleair hair cells. Furthermore patients with FIC 1 disease have reported complaints of disequilibrium. Current standard vestibular testing (Electronystagmography (ENG)) solely tests the function of one of the five subcomponents of the vestibular organ, the horizontal semicircular canal. In patients with a mild phenotype of FIC 1 disease, BRIC type 1, the ENG showed normal responses. An additional vestibular test, the ocular Vestibular Evoked Myogenic Potential (oVEMP) test, can be used to evaluate the function of two other subcomponents, the two otolith organs. In this study we will compare the oVEMP responses of BRIC type 1 patients to responses in normal subjects.

### Study objective

To gain information about the characteristics of the oVEMP response in patients

with BRIC type 1

## Study design

A cohort of BRIC type 1 patients will be tested and the results will be compared to a group of normals.

## Study burden and risks

For this study patients will have to visit the UMCU once for the oVEMP-test and audiometry (in some cases). For the oVEMP-test 5 electrodes will be placed on the face of the patient and an acoustic stimulus will be delivered to the ears with the patient in supine position with raised eyes. The potential risks of the oVEMP-test are very small. The acoustic stimulus can be experienced as uncomfortable, but is not painful and will not damage the auditory system.

## Contacts

### Public

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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

Patients with a mild phenotype of FIC1 disease, BRIC type 1, with 2 known mutations in the ATP8B1-gene and clinically one episode of low or normal  $\gamma$ -glutamyl transpeptidase (GGT) cholestasis.

Age  $\geq$  18 years

## Exclusion criteria

An interfering cause of vertigo

History of eye-motility disorders

Audiometrically defined conductive hearing loss of more than 20 dB NHL at 500 Hz

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	06-07-2009
Enrollment:	10
Type:	Actual

### Medical products/devices used

Generic name:	Toennies Multiliner evoked potential recording system
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Registration: Yes - CE intended use

## Ethics review

Approved WMO

Date: 28-04-2009

Application type: First submission

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date: 09-06-2009

Application type: Amendment

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

## 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**

NL26583.041.09