A Multicentre, Prospective, Longitudinal, Observational Natural History Study to Evaluate Disease Progression in Subjects with Usher Syndrome type 1B (USH1B)

Published: 08-08-2018
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To evaluate the natural progression of disease over time in USH1B patients using visual field testing and best corrected visual acuity.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Eye disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON46147

Source
ToetsingOnline

Brief title
Natural history of Usher syndrome type 1B

Condition

- Eye disorders NEC

Synonym
Usher syndrome type 1B

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: EU

Intervention

Keyword: Natural history, Usher syndrome type 1B, Vision

Outcome measures

Primary outcome

Visual acuity & visual field.

Secondary outcome

IOP

ERG

OCT

Fundusphotographs

VFQ-25

Study description

Background summary

This natural history study is being conducted to understand the progression of disease in USH1B patients as measured by visual acuity and visual field testing and a number of other vision-related assessments.

Study objective

To evaluate the natural progression of disease over time in USH1B patients using visual field testing and best corrected visual acuity.

Study design

Multicenter, prospective, observational.

Study burden and risks

Electrodes for ERG measurements can cause superficial abrasions of the cornea which usually heal spontaneously within one day. Other risks are minimal.

Subjects do not benefit from participation. Due to the extensive measurements, participation can be somewhat exhausting; subjects are encouraged to indicate when they need a break. Study related time: 3 times two days.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Informed consent
Diagnosed with USH1
Molecular diagnosis of USH1B due to MYO7A mutations (homozygotes or compound heterozygotes)

Age >= 8 years
Visual acuity >= 20/640 in at least one eye

Exclusion criteria

Unable to communicate with suitable verbal/auditory and/or tactile sign language
Participation in clinical study with investigational drug in past 6 months
Pre-existing ocular conditions that would interfere with the interpretation of study endpoints (e.g. glaucoma, corneal or significant lenticular opacities, cystoid macular oedema, macular hole) in both eyes
Complicating systemic diseases in which the disease itself, or the treatment for the disease, can alter ocular function
Prior ocular surgery within 3 months

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):	12-12-2018
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	08-08-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL66164.078.18