

Neural origin of slow vision: contributions of the central and peripheral nervous system.

Published: 28-08-2014

Last updated: 21-04-2024

To study neuronal and ophthalmological characteristics of a newly detected clinical entity called slow vision which hampers visual perception and attention of the affected patients.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Vision disorders
Study type	Observational non invasive

Summary

ID

NL-OMON41172

Source

ToetsingOnline

Brief title

The origin of slow vision

Condition

- Vision disorders
- Neurological disorders of the eye
- Cognitive and attention disorders and disturbances

Synonym

slow vision, slow visual processing speed

Research involving

Human

Sponsors and support

Primary sponsor: Radboudumc

Source(s) of monetary or material Support: Donders Instituut

Intervention

Keyword: visual attention, visual disorder, visual perception, visual processing speed

Outcome measures

Primary outcome

- Electrophysiological responses of the retina and the cortex to visual stimuli.
- Optical responses of the photoreceptors to visual stimuli.
- Performance on computer-based tasks testing central vision, visual attention and motion detection.
- Electrophysiological and haemodynamic neural responses of the brain to visual stimuli.

Secondary outcome

Diagnostic value of the speed-acuity to discriminate between patients and controls.

Auditory processing speed using a computer-based task in order to exclude the possibility that processing speed in general is disrupted in SV rather than specifically in the visual modality.

Study description

Background summary

A number of patients who seek help at the Department of Ophthalmology Radboudumc experience problems of delayed or slow processing of visual information at home, school, work or in traffic. For example, patients can complain about their inability to read subtitles before they disappear from the screen. Although these patients face substantial hamper in daily life, they do not meet current diagnostic criteria of any known ocular or neurological

disorder or of visual impairment. In fact, the source of their problems is still unknown. There is also no current treatment option for these patients. To fill this gap, we want to investigate their visual and attentional systems to learn more about the origin of their symptoms thereby providing information necessary for the development of diagnostic criteria and treatment.

Study objective

To study neuronal and ophthalmological characteristics of a newly detected clinical entity called slow vision which hampers visual perception and attention of the affected patients.

Study design

Observational case-control study.

Study burden and risks

We will measure processing throughout the visual system using a number of non-invasive measurements. The measurements will last about 8 hours in total. To limit the burden on participants, we have divided the study into three sessions: 1) ophthalmological examination (routine ophthalmological examination and cognitive VEP, mERG) and psychophysics, 2) fMRI session and 3) MEG session. The sessions will be carried out separately. Sessions 2 and 3 will only be done if results of session 1 show differences between patients and controls on the main psychophysical tasks (computer based attentional and perception tasks) or on the cognitive VEP. Session 1 will last approximately 5 hours including breaks. Although all measurements will be easy to perform, participants will have to concentrate, fixate and sometimes respond to visual stimuli. Some of the measurements could be experienced as somewhat uncomfortable by the participant. mERG measurements require eye drops (1% tropicamide or 2.5% phenylephrine in case of allergies) to increase signal to noise ratio (SNR). Additional eye drops consisting of 4 mg/ml oxibuprocaine are used to locally anaesthetize the eyes. This is part of a routine procedure applied in electrophysiology measurements at the ophthalmology department of Radboudumc and in accordance with ISCEV standards (Hood et al., 2012). Subjects should not rub their eyes for at least one hour after administration of the oxibuprocaine drops, and they are not allowed to drive until the effects of the drops have worn off (i.e. 2-4 hours after installation). Sessions 2 and 3 will each last about 1.5 hours and will involve measuring brain activity using MRI and MEG, respectively. During these sessions, participants will have to sit or lie very still while performing psychophysical tasks similar to those used in session 1. Risks associated with the aforementioned techniques are minimal if procedures are followed carefully. No significant risks are to be expected for cognitive VEP. There is a minimal risk of corneal erosion caused by the mERG electrode.

However, this type of damage rarely occurs and is known to heal quickly and completely. Risks associated with MRI and MEG mainly revolve around metals and electromagnetic implants. We will therefore thoroughly screen participants beforehand with a standard screening questionnaire provided by the Donders Centre for Cognitive Neuroimaging. If a patient reports contraindications for MRI and/or MEG, he will be excluded from session 2 and/or 3. Controls will be screened before inclusion and again before session 2 and 3. If they report any contraindications for MRI and/or MEG, they will be excluded from the study. At the time of this study, participants will not benefit. However, it will raise awareness of the existence of SV, describe its neurophysiological and behavioural characteristics, provide the first steps in elucidating its causes, and guide development of diagnostic criteria and treatment which will eventually benefit the patients.

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

- Between 18 and 65 years old
 - Visual acuity ≥ 0.6
 - Normal birth weight (i.e. ≥ 2500 g) and pregnancy duration (i.e. ≥ 37 weeks);Patients:
Probable slow vision: Complaints related to slow visual processing, for example:
 - Reading slowly
 - Being unable to read subtitles(e.g. during movies) in time (i.e. before they disappear from the screen).
 - Not being able to quickly find objects in a pile (for example in a full drawer).
 - Not being able to quickly recognize a face in a crowd.
- Or, abnormally slow in identifying optotypes during standard ophthalmological examination as assessed by the optometrist/ophthalmologist.

Exclusion criteria

- Any visual field defect in central 30° with statistical significance of more than 0,95, determined with Humphrey perimetry
- Ocular surgery other than uneventful cataract surgery, within 3 months before inclusion to our study
- Diagnosis of congenital or acquired optic nerve head pathology.
- Diagnosis of manifest glaucoma with defects in the visual field.
- Diagnosis of a neurodegenerative disorder or high-energy brain trauma.;Patients:
Only for mERG:
 - Presence of contraindications reported by the participant for tropicamide and phenylephrine
 - Pregnancy or breast feeding
- Hypersensitivity to oxybuprocain;Only for MRI and MEG sessions:
 - Exclusion criteria determined by the Donders Centre for Cognitive Neuroimaging regarding safety and/or signal interference.;
- Controls:
 - Presence of contraindications reported by the participant for tropicamide and phenylephrine
 - Pregnancy or breast feeding
 - Exclusion criteria determined by the Donders Centre for Cognitive Neuroimaging regarding safety and/or signal interference.
 - Hypersensitivity to oxybuprocain

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:	Recruiting
Start date (anticipated):	19-06-2015
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO	
Date:	28-08-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	14-01-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	27-08-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	29-04-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	04-07-2016
Application type:	Amendment

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	NL49098.091.14