Visual competition for saccade target selection in the recovered field of hemianopia patients following visual restoration therapy.

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To study the neurological changes that explains the recovering of visual field defects after visual restoration therapy.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neurological disorders of the eye
Study type	Observational non invasive

Summary

ID

NL-OMON41770

Source
ToetsingOnline

Brief title
Visual competition after visual restoration therapy

Condition

- Neurological disorders of the eye

Synonym
cortical blindness, Hemianopia

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Marie-Curie fellowship;HealthPAC

Intervention

Keyword: Hemianopia, Saccade target selection, Visual decision-making, Visual perception

Outcome measures

Primary outcome

- Performance on a computer-based task testing saccade selection measured with

Eyelink II eye-tracker (SR Research Ltd., Mississauga Ontario, Canada)

Secondary outcome

n.v.t

Study description

Background summary

Visual information processing is of critical importance in everyday life activities. This becomes clear when part of the visual field gets damaged. Visual field defects can arise due to post-chiasmatic lesions for example caused by vasculaire incidents, carnio-cerebral trauma, hypoxia and inflammatory processes. These patients, also called hemianopia patients, will encounter problems in daily living due too limitations in reading, visual navigation (cycling, driving a car) and visual identification (recognition of objects and persons).

Spontaneous recovery of hemianopia patients occurs when the inflammations in the damaged areas diminish. However, the chance of spontaneous recovery decreases rapidly after the accident and become very rare after a couple of months. Several studies show that intensive visual training, like visual restoration therapy, can support this recovery to increase the change in extent and depth of the visual field defect. This recovered visual field will eventually improve the quality of daily living of these patients.

Certain patients report no improvements of daily living after the training. Even though the standard perimetrical test show an enlarged visual field including visual discrimination of letters, shapes and colours. Therefore, it becomes important to find supplementary measurements to map the visual changes caused by the training. The visual system is known to have several levels of competition between different parts of the visual field. The standard perceptual measures like perimetry give little insight about this aspect of the

recovery. It is very well possible that for some patients the recovered visual field is no match for the competition in the visual attention with non-damaged areas.

Our pilot study is designed to get insight about the contribution of the recovered field in the visual decision-making process and in this way to get an understanding of the recovery of competition abilities of the recovered field. Previous studies in our group showed that in healthy participants the choice to make an eye saccade between one of two identical goals, is based on a competitive choice mechanism with feedback inhibition. Our goal is to map, if this saccadic decision-making in the recovered visual field of hemianopia patients comes about in a similar manner or shows deviations.
Any deviations in this saccadic decision-making would suggest an inferior role of the recovered visual field with respect to the undamaged visual field.

Study objective

To study the neurological changes that explains the recovering of visual field defects after visual restoration therapy.

Study design

Each participant is his/her own control in a single-blind, randomised trial.

Study burden and risks

We will indirectly measure neural processes in the visual system using a non-invasive, psychophysic task. The whole measurement will last up to 5 hours including breaks. We divided the study into three sessions spread over the day to limit the burden on the participants. This three sessions include; 1) ophthalmological examination (Goldman perimetry and Humphrey perimetry), 2) a first psychophysic session to determine the personal bias and 3) a second psychophysic session which is the primary measurement.

Session 1 will determine if we will continue the experiment depending on the results. Hereby, we will look if the participant still has a stable recovered field measured with the Goldman and Humphrey perimetry. Throughout this session the participant will be asked to concentrate, fixate and respond to a dot light-stimuli presented in the visual defect and healthy part. No risks or burdens are involved in both perimetrical tests.

Session 2 and 3 will last 0.5 and 1 hour, respectively and will involve behavioural measurements using a computer-based task and an eye-tracker. During this sessions, the participants will be asked to concentrate, fixate and respond to a visual light-stimuli by performing a saccade towards to brightest stimuli. We will use a bite board to ensure that the participant head position

throughout the both sessions.

There are no risks associated with the aforementioned technique. The individually tailoring of the bite boards will take about 2 minutes and is hardly uncomfortable. At this time, the study will not have direct benefits for the participants. It does give however a possibility to 1) give insight about the neurophysiological characteristics of the recovered field (including the recovered visual field in normal or deviating networks of visual-motor decision-making processes) or 2) if there is a correlation between the deviations and the quality of daily life of patients.

Therefore, this experiment will give the first steps of understand the recovery processes and a guide towards the development of improved (possible saccade related) treatment which eventually will benefit patients.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein-Noord 21
Nijmegen 6525 EZ
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein-Noord 21
Nijmegen 6525 EZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Age 18 - 75 year.
- Patients with visual field defects as consequence of post-chiasmatic cerebro-vascular accident.
- Patients with a detectable recovered visual field due to the visual restoration therapy. (registration number: NL38477.091.11 en NL42031.091.13).
- Signed permission to be contacted for follow-up studies (registration number: NL38477.091.11 en NL42031.091.13.
- Signed informed consent of the patient.

Exclusion criteria

- Presence of visual neglect (tested with character line bisection).
- Presence of neurological or psychiatric impairments.
- Visual correction, depending on the sort of glasses.
- Recurrent stroke during or after the visual restorative therapy.
- No (partial) recovery of the field defect following training

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-06-2015
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	18-02-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL51001.091.14

Study results

Date completed:	30-03-2017
Actual enrolment:	20