Stimulux: Optimizing blue light exposure on the retina for non-image forming effects and visual comfort

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Main objective of the study is to determine the optimal angle of illumination and intensity of blue LEDs fitted to glasses, to induce non-visual responses

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON38764

Source
ToetsingOnline

Brief title
Stimulux

Condition

- Other condition

Synonym
nvt

Health condition

nvt

Research involving
Human

Sponsors and support

Primary sponsor: Janssen-Cilag
Source(s) of monetary or material Support: Janssen Pharmaceutica NV

Intervention

Keyword: blue light, non-visual responses of light, visual comfort, well-being

Outcome measures

Primary outcome

Study 1: pupil size changes in response to light exposure. Study 2: melatonin

suppression in response to light

Secondary outcome

visual comfort, alertness and performance in response to light exposure

Study description

Background summary

Stimulux® is a new medical product to be designed as a light treatment device. It consists of glasses fitted with blue LED lights. Main research question of the study is: Is the angle of illumination important to elicit non-visual responses and if so, are the effects of different non-visual responses different for different illumination angles.

Study objective

Main objective of the study is to determine the optimal angle of illumination and intensity of blue LEDs fitted to glasses, to induce non-visual responses

Study design

Within-subject, randomly assigned crossover study-design.

Intervention

Blue LED light exposure, LEDs fitted to glasses, of varying intensity and varying angle of illumination. In study 1, subjects will be exposed to pulses

of 30 sec. In study 2, subjects will be exposed to a selection of intensities and angle of illumination, based on the results in study 1, with a light pulse duration of 1.5 hours.

Study burden and risks

There are no risks involved from participating in the study. Stimulux is tested to be safe by two independent, internationally expert safety institutes, there is no blue light hazard risk. Visual comfort and complaints will be monitored throughout and subjects will undergo an eye check before and after study 2. Time investment and burden of the healthy individuals is relatively low. In study 1, participants have to come to the institute on one morning of afternoon and the experiment lasts 2 hours. There will be enough breaks to make it comfortable for the subjects, since they have to sit still to do the measurements. Study 2 takes a bit more time. Subjects are asked to come to the institute five times, for 3.5 hours each time, in the evening. this will result in some sleep deprivation. The measurements, like saliva collection, and simple ratings and performance tests on the computer will be of very low burden.

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

Healthy men and women; ages between 20-35y to avoid the lens changes that occur with aging
Subjects should be fluent in Dutch (because of the use of Dutch rating scales). Signed informed consent.

Exclusion criteria

You suffer from (chronic) disease (physical or psychological)
You suffer from sleep disorders (mild sleep complains are not a problem)
You are visually impaired or you had undergo eye surgery in the last year (contact lenses and glasses are not a problem)
You are taking medication or have taken long-term effects medication in the 3 months prior to participation, which are known to increase the sensitivity to light (see leaflet)
You use regular sleep medication or stimulants
Two or more time zones transmeridian flights one month prior to participation
Shift work during the 3 months prior to participation
Colour blindness
Excessive daily amounts of caffeinated drinks (>8 cups/drinks per day. E.g., coffee, cola, energy drinks)
Alcohol (more than 3 glasses on a working day) or drug problems
The use of melatonin

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-05-2014
Enrollment:	18
Type:	Actual

Ethics review

Approved WMO

Date:	27-03-2014
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	NL45834.042.13