Phase advancing the circadian system with short pulses of blue light

Published: 24-06-2010
Last updated: 30-04-2024

Main objective of the study is to find out whether short duration pulses of blue light at high intensity in the morning are capable of inducing a phase advance of the circadian system.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON34171

Source
ToetsingOnline

Brief title
GoShort

Condition

- Other condition

Synonym
evening types, late chronotypes

Health condition

circadian alignment

Research involving
Human

Sponsors and support

Primary sponsor: Philips Consumer Lifestyle
Source(s) of monetary or material Support: Philips Consumer Lifestyle B.V.

Intervention

Keyword: chronotype, circadian system, phase shift, short wavelength light

Outcome measures

Primary outcome

Main study parameter is the rhythm of melatonin concentration in saliva. A

shift in phase markers of the melatonin rhythm is interpreted as a shift of the

endogenous circadian pacemaker.

Secondary outcome

(1) Ambulatory rest-activity rhythms

(2) Subjective ratings, e.g. sleepiness, headache, chronotype

Study description

Background summary

Light in the morning is able to induce phase advances of the endogenous clock, but optimal parameters about light duration, intensity and colour need to be specified. No information is available about how short light pulses can be that are still able to induce shifts. Available laboratory studies show that 6.5h of light is capable of inducing shifts, and some information is available about light pulses of 2 hours. In theory, a high intensity shorter light pulse in the short-wavelength range should also be capable of inducing phase advances. In addition optimal timing of the light pulse is important. In the laboratory we are able to determine endogenous phase by measuring the melatonin rhythm. To come to a practical measurement in the field, we will investigate other methods to find out what best predicts endogenous phase.

Study objective

Main objective of the study is to find out whether short duration pulses of blue light at high intensity in the morning are capable of inducing a phase advance of the circadian system.

Study design

In a randomized controlled, within-subjects, intervention study we will expose people either to short duration blue light pulses or to longer duration blue light pulses in the morning. During the control week the natural course of endogenous circadian phase will be measured and compared with the pattern in the experimental weeks.

Study burden and risks

All subjects will participate in all conditions. Subjects are housed during one night in our facility to perform baseline measurements. During the rest of the time they perform the measurements at home. During the timing of saliva collection they should obey to instructions about their environmental light exposure (dim light) and their food and drinks intake. They receive instructions on a window where sleep is allowed. Nature and extent of the burden per subject are minimal and there are no real risks associated with participation. The major concern in these types of studies is the ocular safety of using a blue light emitting lamp. To verify the safety of the used light source the device was submitted for Ocular Radiation Hazard testing by the Commission International de l*Eclairage (CIE). The device was determined to be safe with even at a factor of 100 times the normal usage recommendations. The subjects may slightly benefit from the treatment by obtaining a phase advance of their circadian system. The benefits for science and clinical practice in the future are large and make this study innovative and exciting.

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 between ages 20 and 30 y with a median to late sleep phase.

Exclusion criteria

• Two time zones transmeridian flights (or more) one month prior to participation
• Regularly taking naps (on average more then 2 per week)
• Shift work during the last 3 months
• Colour blindness
• Visually impaired
• Ophthalmologic complaints or a history of eye surgery
• Somatic and psychiatric diseases (depressed mood rating BDI-II-NL >8
• History of chronic diseases
• Excessive daily amount of caffeinated drinks
• Alcohol or drug problems
• Regular medication 3 months prior to participation
• Smokers
• Habitual midsleep later then 6:07 (>5% extreme late chronotype)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-07-2010
Enrollment:	14
Type:	Actual

Medical products/devices used

Generic name:	Go LITE BLUE HF 3330
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	24-06-2010
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	NL32190.042.10