MyopiaX Treatment for the Reduction of Myopia Progression in Children and Adolescents: Safety and Efficacy Investigation

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Primary objectiveTo evaluate the effects of treatment with MyopiaX on the rate of myopia progression in children and adolescents as reflected in spherical equivalent refraction and axial length changes at 6months relative to baseline.Secondary...

Ethical review	Approved WMO
Status	Completed
Health condition type	Vision disorders
Study type	Interventional

Summary

ID

NL-OMON52343

Source
ToetsingOnline

Brief title
MyopiaX-1

Condition

- Vision disorders

Synonym
Nearsightedness

Research involving
Human

Sponsors and support

Primary sponsor: Dopavision GmbH

Source(s) of monetary or material Support: Dopavision GmbH;Berlin;Germany

Intervention

Keyword: Myopia, Nearsightedness, Software App, Virtual reality

Outcome measures

Primary outcome

Change in spherical equivalent refraction and axial length from baseline to 6

months

Secondary outcome

not applicable

Study description

Background summary

The prevalence of myopia, or nearsightedness, has increased at an alarming rate over the past two decades and is expected to continue accelerating in the coming years. It has been predicted that close to 50% of the world*s population will be nearsighted by 2050 (Holden et al., 2016) and recent research suggests that restrictions during the COVID-19 pandemic may exacerbate this trend due to limited time outdoor (J. Wang et al., 2021).

Myopia is typically characterized by excessive ocular growth that increases the risk of serious, sight-threatening complications in adulthood, including cataract, glaucoma, retinal detachment, and myopic maculopathy. The risk of developing any of these comorbidities increases with myopia severity (Flitcroft, 2012; Haarman et al., 2020). Myopia is quickly becoming a global health problem and there is a growing need for more effective interventions to slow its development and progression.

Myopia is a progressive disease and children with early onset are at particular risk of complications associated with myopia, as progression over time might result in high myopia and myopic macular degeneration (Grzybowski et al., 2020). Currently, there is no standard treatment for myopia progression, however a range of myopia control approaches is available, including active spectacles, contact lenses, and pharmacological treatments (Huang et al., 2016; Prousali et al., 2019; Wildsoet et al., 2019).

While atropine and various contact lens types, including orthokeratology, have been shown to be effective against myopia progression (Huang et al., 2016; Prousali et al., 2019), both treatments are accompanied by several risks that should be taken into consideration. Even if applied at low dosages, atropine use is off label and has considerable side effects, such as photosensitivity, poor near visual acuity, and temporary stinging or burning (Gifford et al., 2019; Gong et al., 2017). The side effects of orthokeratology and other contact lenses include mild blurry vision (Gifford et al., 2019), mild corneal erosion, corneal staining, lens binding, reduced tear film (Prousali et al., 2019), and infectious keratitis (Vagge et al., 2018).

Infectious keratitis can lead to corneal scars, which require surgical treatment in 10% of cases (Prousali et al., 2019).
The recent approval of myopia control spectacle lenses, offer a new approach with an acceptable
benefit-risk profile (H. Y. Zhang et al., 2020). Despite this new therapeutic option in the
management of progressive myopia, the unmet need for additional, and potentially complementary
therapies remains, as these lenses do not completely stop myopia progression, and even when
prescribed, are not accessible for everyone, maybe difficult to fit and/or are not consistently worn
by children.
The present clinical trial will evaluate treatment with MyopiaX, which aims to slow myopia progression in a non-invasive and low-risk manner. MyopiaX is a digital treatment that delivers flickering blue light to the optic nerve head using a smartphone-compatible game. Played using a virtual reality (VR) headset, there is almost no observable difference between MyopiaX and any other video game, as the blue light stimulus is positioned so that it is not visible to the user.

The intensity of the blue light stimulation does not surpass the normal illuminance of commercially available smartphones. The blue light used in MyopiaX targets the optic nerve head in order to minimize any adverse effects to the retina. The goal of MyopiaX is to stimulate the axons of melanopsin-containing intrinsically photosensitive retinal ganglion cells (ipRGCs) at the optic nerve head with blue light in order to increase the melanopsin-mediated release of retinal dopamine, which is an important neurotransmitter that contributes to eye growth regulation.

Increased levels of dopamine can slow eye growth and, as a result, reduce the rate of development or progression of myopia (Chakraborty et al., 2019). The required usage of MyopiaX is twice a day for about 12 minutes, including set up and removal of the device, breaks between levels, and a total of 10 minutes of active stimulation with blue light.
The objective of the present clinical investigation is to evaluate the signals

of effect, the safety and tolerability of MyopiaX in slowing the progression of myopia through stimulating the axons of melanopsin-containing intrinsically photosensitive retinal ganglion cells (ipRGCs) at the optic nerve head with blue light.

This study is also aimed at evaluating the safety of MyopiaX and its acceptability to parents/guardians and their children.

Study objective

Primary objective

To evaluate the effects of treatment with MyopiaX on the rate of myopia progression in children
and adolescents as reflected in spherical equivalent refraction and axial length changes at 6
months relative to baseline.

Secondary objectives

- Evaluate the safety of treatment with MyopiaX in terms of incidence of device related adverse events (AEs), changes in visual acuity, and fundus.
imaging data at the beginning of the trial (baseline) and during the treatment period.

Exploratory Objectives
- Evaluate the effect of MyopiaX relative to the effect of myopia control spectacles after six
months of treatment
• Evaluate the effect of MyopiaX + myopia control spectacles relative to the effect of myopia
control spectacles only (months 6 - 12)
• Explore the effect of MyopiaX on retinal and choroidal (such as choroidal thickness) imaging
parameters under treatment
• Assess device usability information using a user feedback questionnaire.

Study design

This is a prospective, randomized, controlled, single-masked, multicenter, international trial that
aims to evaluate the effect of MyopiaX treatment in myopia progression

Trial participants will be randomly assigned 2:1 to the MyopiaX treatment or myopia control
spectacle lenses treatment

The study is single-masked, investigators assessing the outcome measures (clinical assessors) at
each site will be masked towards the allocated treatment. The study subjects that are already
randomized, are also masked to their study treatment (MyopiaX device or sham device), whereas
the newly randomized subjects will be unmasked to their study treatment allocation (MyopiaX or
spectacle lenses).

Intervention

The blue light stimulation which is controlled by MyopiaX and then emitted by the smartphone is delivered for 10 minutes (active stimulus duration) per session. Participants receive a maximum of 10 minutes of blue light at their optic nerve head depending on the blinking and fixation stability. Each session consists of different levels lasting for 30-120 s. Breaks of 15-20 s are included between levels. Including the time needed to setup the device, the inter-level breaks, the active stimulus duration, and the removal of the device, the overall session duration is about 12 minutes.

A session will be counted as successful if the participant receives at least 8 minutes of blue light stimulation (i.e., excluding the breaks between levels), and his/her score indicates active playing.. The CIP section 6.5.3. describes the procedures implemented when participants are not performing the sessions as intended. Detailed information about the device and the treatment is provided in the instructions for use (IFU) and the user manual.

Study burden and risks

The risks associated with the treatment do not surpass the risks associated with the domestic use of electronic devices (smartphone, tablets, computers, VR) for the children in the clinical investigation.

Participating in the study does not imply a higher risk for the children than attending the regular check-ups that myopic children usually undergo to control myopia progression. Furthermore, the medical examinations are implemented in such way that any detrimental ocular changes can be detected early, thus minimizing risks and ensuring prompt MyopiaX interruption and treatment if necessary.

Furthermore, study participants that present, in the investigators` clinical judgment an unacceptable rate of progression, clinically validated therapies will be recommended thus ensuring that participants in the trial have access to the clinically available and validated methods to manage myopia.

Contacts

Public
Dopavision GmbH

Krausenstrasse 9-10
Berlin 10117
DE
Scientific
Dopavision GmbH

Krausenstrasse 9-10
Berlin 10117
DE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Children (2-11 years)

Inclusion criteria

- Myopic children (-0.75 to -5.0 D SER, least myopic meridian -0.50 D in each eye)
- At least VA 0.2 LogMAR in each eye
- Age: 6 - 12 years old
- Good tolerability of test session with VR system
- Binocular adequacy as tested with VR
- Ability to understand treatment and give valid assent

Exclusion criteria

- Concomitant or previous therapies for myopia

-Eye diseases/conditions:
- Anisometropia >= 1.5 D
- Astigmatism >= 3 D
- Ophthalmological comorbidities
- Optic nerve abnormalities
- Suspicion of syndromic or monogenetic myopia
- Systemic illnesses affecting eye health, eye growth, and/or refraction
- Any illnesses affecting dopamine function (e.g., sleep disorder, ADHD, Parkinson Disease, and autism spectrum disorders)
- Medication affecting dopamine function, accommodation, pupil size, or having an impact on the ocular surface (topical ocular medications)
- Participation in other clinical studies
- Medical history (or family history) of photosensitive epilepsy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	17-03-2023
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	MyopiaX
Registration:	No

Ethics review

Approved WMO Date:	15-06-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-01-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	02-05-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-09-2023
Application type:	Amendment
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
ClinicalTrials.gov	NCT04967287
CCMO	NL77861.000.21