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Visual performance of three myopia control spectacles for children in China

Submission date
06/06/2023

Recruitment status
No longer recruiting

Registration date
08/06/2023

Overall study status
Completed

Last Edited
16/07/2024

Condition category
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The purpose of this observational study is to evaluate the 'visual performance' of 3 myopia (short-sightedness) control spectacle lenses worn for 1 to 2 weeks period. Visual performance in this study means how well the wearers can see, how quickly they can read and if they see halos through the spectacle lenses.

Who can participate?
Healthy myopic children aged 6 to 14 years old with non-diseased eyes.

What does the study involve?
There are up to five study visits over an eight-week period, one visit every 2 weeks. Participants will be wearing 3 different types of commercially available myopia control spectacle lenses in their prescription in a random fashion for 1 to 2 weeks. Each visit will be about 1.5 hour. At each visit, using Aston Vision iPad App, participants will be reading letters on a letter chart to measure vision, reading sentences to measure reading speed, to see if halos are present and obtaining feedback on their experience each of the spectacles worn using questionnaires.

What are the possible benefits and risks of participating?
The participants may not directly benefit from participating in the study. They will have the opportunity to try three different types of myopia control spectacles and choose the one they prefer. The examination and assessment of their eyes are provided at no cost and may be considered beneficial to know their current eye condition.

The risk of participating will be similar to those of normal spectacle lens wear, such as blurred vision, headache or discomfort due to spectacle frame fit. If participants experience any of these, they should let the investigator know.

Where is the study run from?
Zhongshan Ophthalmic Center of Sun Yat-Sen University (China)

When is the study starting and how long is it expected to run for?
November 2022 to September 2023

Who is funding the study?
SightGlass Vision, Inc (USA)

Who is the main contact?
Dr Lucill Wang (Sponsor), lwang@sightglassvision.com
Dr Xiang Chen (Study Investigator), chenxiang@gzzoc.com

Contact information

Type(s)
Principal investigator

Contact name
Prof Xiang Chen

ORCID ID
https://orcid.org/0000-0002-9551-9408

Contact details
Zhongshan Ophthalmic Center of Sun Yat-sen University
Guangzhou
China
510060
+86 20-66610720
chenxiang@gzzoc.com

Type(s)
Scientific

Contact name
Dr Lucill Wang

Contact details
4970 El Camino Real, Suite 100
Los Altos
United States of America
94022
+1-707-530-2523
lwang@sightglassvision.com

Additional identifiers

Protocol serial number
CPRO-2211-001

Study information

Scientific Title

Observational Study on visual performance of three different myopia control optical lenses for children in China

Acronym
CEDAR-2

Study objectives
Myopia control spectacle lenses visual performance tested will be equivalent.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/01/2023, Zhongshan Ophthalmic Center of Sun Yat-sen University Ethics Committee (54 Xianlie Nan Road, Guangzhou, Guangdong Providence, P.R. China; +86 20-66610720; zocethics@163.com), ref: 2023KYPJ002

Primary study design
Interventional

Study design
Single-center randomized double blind controlled three-test arm cross over study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Myopia control in myopic children

Interventions
The purpose of this study is to compare the 'visual performance' of the three myopia control spectacle lenses (DOT, DIMS, CARE) and their habitual single vision spectacles. Participants will use all three spectacle lenses matching their prescriptions in a randomized sequence (computer generated). Each spectacle will be worn for 1 to 2 weeks. Measurements at baseline with their habitual spectacle and follow up visits with each myopia control spectacle will include visual acuity, reading speed, near contrast sensitivity, halometry and subjective questionnaires.

Intervention Type
Device

Phase
Phase III/IV

Drug/device/biological/vaccine name(s)
Diffusion Optics Technology (DOT), Defocus Incorporated Multiple Segments (DIMS), Cylindrical Annular Refractive Element (CARE).

Primary outcome(s)
Visual performance measured using Aston Vision iPad App (visual acuity, reading speed, near contrast sensitivity, and halometry) of test spectacles at baseline and after 1-2 weeks of wear in

comparison with habitual spectacles.
1. Visual acuity in logMAR (number of letters read on the letter chart)
2. Reading speed in maximum words per minute
3. Near contrast sensitivity at @ 1.5, 3.0, 6.0, 12.0 and 18.0 cycles per degree (cpd)
4. Halometry in halo radius in degrees

Key secondary outcome(s)
Visual performance measured using Aston Vision iPad App at baseline and after 1-2 weeks of wear with 3 different test spectacles:
1. Visual acuity in logMAR (number of letters read on the letter chart)
2. Reading speed in maximum words per minute
3. Near contrast sensitivity at @ 1.5, 3.0, 6.0, 12.0 and 18.0 cycles per degree (cpd)
4. Halometry in halo radius in degrees

Completion date
01/09/2023

Eligibility

Key inclusion criteria
1. Myopic children aged 6 to 14 years, with spherical equivalent refraction (SER) -0.75 D to -4.00 D (by cycloplegic autorefraction) in each eye.
2. Best corrected visual acuity (BCVA) by manifest refraction of +0.10 logMAR (0.8 Snellen equivalent) or better in each eye.
3. Pass stereopsis and color vision screening.
4. Ability to comply with all study procedures, including assessments of visual performance with assigned correction.
5. Willingness to wear assigned spectacles for the duration of the study.
6. The subject's parent(s) or legal guardian(s) must read, understand and sign the ICF and receive a fully executed copy.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 Years

Upper age limit
14 Years

Sex
All

Total final enrolment

Key exclusion criteria
1. Prior use of any myopia control approaches, such as atropine, multifocal contact lenses, orthokeratology (ortho-K), or other spectacle lenses designed for myopia control including peripheral defocus, bifocal, and progressive addition lenses.
2. Astigmatism worse than -1.25 DC (by manifest refraction) in either eye.
3. Anisometropia (SER manifest refraction) greater than 1.00 D.
4. Amblyopia in either eye.
5. Strabismus by cover test at far (4 m) or near (40 cm) wearing distance correction.
6. Any ocular or systemic conditions that could influence refractive development or status [e.g., keratoconus, congenital glaucoma, ocular trauma, diabetes, Marfan syndrome or other connective tissue disorder, Down syndrome, family history of poor night vision (to prevent against enrolling subjects with congenital stationary night blindness).
7. Participation in any investigational clinical study within 30 days of the Screening visit.

Date of first enrolment
01/04/2023

Date of final enrolment
15/06/2023

Locations

Countries of recruitment
China

Study participating centre
Zhongshan Ophthalmic Center of Sun Yat-Sen University
54 Xianlie Nan Road
Guangzhou
China
510060

Sponsor information

Organisation
SightGlass Vision

Funder(s)

Funder type
Industry

Funder Name
SightGlassVision

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication, Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results			16/07/2024	No	No