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Clinical investigation of soft contact lenses

Submission date 30/08/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 13/09/2024	**Overall study status** Completed	
Last Edited 13/09/2024	**Condition category** Eye Diseases	

Plain English summary of protocol

Background and study aims
The number of adolescents with myopia (short-sightedness) has been increasing very rapidly over the last 10 - 20 years. The concern is that short-sighted eyes are more likely to develop ocular pathology (eye disease) than normal eyes from the age of 60+. Therefore, various methods are being developed to minimise short-sightedness and prevent potential problems later in life, one such method is the use of special design contact lenses. This study aims to compare the acceptance of a new design of contact lenses with a currently marketed design.

Who can participate?
Children aged between 8 and 18 years old who have experience with soft contact lens wear and can insert and remove soft contact lenses

What does the study involve?
The participants will attend a total of four visits as described below.
The first phase will be conducted as a prospective, randomized (order of testing of the two study contact lenses), double-masked one-week cross-over. The second phase will be a double-masked parallel group comparison of the lenses after one month of use of the second lens type.
i. Visit 1 for screening, enrolment baseline and for collection of dispensing baseline data for the first contact lens type, randomly allocated either to the test or control contact lens to be worn for one week;
ii. Visit 2 for collection of the follow-up data after one week of use of the first contact lens type and dispensing baseline data for the second lens type;
iii. Visit 3 for collection of the follow-up data after one week of use of the second contact lens type and providing additional lenses for an additional three weeks of lens wear of the second lens type.
iv. Visit 4 for collection of the follow-up data after one month of use of the second contact lens type.

What are the possible benefits and risks of participating?
Participants have the opportunity to try contact lenses to help their vision and control the progression of their myopia.
Any contact lens wear comes at the risk of corneal infection, but the incidence rate is very low.

Where is the study run from?
Ocular Technology Group - International (OTG-i)

When is the study starting and how long is it expected to run for?
June 2023 to February 2025

Who is funding the study?
CooperVision International Limited

Who is the main contact?
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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
333019

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ID23-34 CV23-02, IRAS 333019

Study information

Scientific Title
Clinical investigation of Buttermere (LENS271) soft contact lenses

Study objectives
The first co-primary hypothesis will be to test for any statistically significant difference in lens absolute decentration of Buttermere test contact lens vs MiSight® 1day control contact lens.
The second co-primary hypothesis will be to test for any statistically significant difference in contact lens centration clinical rating expressed in a dichotomous scale (optimal vs. non optimal) of Buttermere test contact lens vs MiSight® 1day control contact lens.
The third co-primary hypothesis will be to test for any statistically significant difference in contact lens movement at blink clinical rating expressed in a dichotomous scale (acceptable vs. non-acceptable) of Buttermere test contact lens vs MiSight® 1day control contact lens.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 28/06/2024, South West - Central Bristol Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8197; centralbristol.rec@hra.nhs.uk), ref: 24/SW/0055

Study design
Randomized double-masked prospective study

Primary study design
Interventional

Secondary study design
Phase01: Randomized cross over trial / Phase02:Randomized parallel trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Myopia

Interventions
The study will be a randomized, double-masked prospective daily disposable study involving four study visits over approximately five weeks of wear, consisting of a 1-week crossover phase followed by a parallel-group phase where the participants will continue to use the second randomised contact lens type for an additional three weeks.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Buttermere (LENS271) contact lenses, MiSight® 1-day contact lenses

Primary outcome measure
The hierarchical primary outcome measures that follow will be assessed at one-week follow-up visits after at least three hours of wear:
1. Total absolute decentration from pupil centre in mm measured using slit lamp biomicroscope with a digital recording attachment during the visit
2. Contact lens centration clinical rating measured using a forced choice clinical scale during the visit
3. Contact lens movement at blink clinical rating measured using a forced choice clinical scale during the visit

Secondary outcome measures
The are no secondary outcome measures

Overall study start date
15/06/2023

Completion date
28/02/2025

Eligibility

Key inclusion criteria
1. Age 8 to 18 years; at least half the population will be children or adolescents aged 8 to 15 years
2. Have experience with soft contact lens wear and able to insert and remove soft contact lenses
3. Parent/guardian and participant have read and understood the Participant Information Sheet
4. Parent/guardian and participant have read, signed and dated the Informed Consent and Assent (when applicable)
5. Best corrected visual acuity of at least 20/25 in each eye
6. Have normal eyes except for the need for visual correction
7. Spectacle refraction:

7.1. Age 8 to 12: -0.75D to -4.00D spherical equivalent, with cylinder ≤ -0.75D and maximum anisometropia of <1.00D
7.2. Age 13-18: -0.75D to -7.00D spherical equivalent, with cylinder ≤ -0.75D and maximum anisometropia of <1.00D
8. Be willing and able to adhere to the instructions set in the clinical protocol and maintain the appointment schedule

Participant type(s)
Healthy volunteer

Age group
Child

Lower age limit
8 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
90

Total final enrolment
80

Key exclusion criteria
1. Acute and subacute inflammation or infection of the anterior chamber of the eye
2. Any eye disease, injury, or abnormality that affects the cornea, conjunctiva, or eyelids
3. Severe insufficiency of lacrimal secretion (dry eyes)
4. Corneal hypoesthesia (reduced corneal sensitivity), if not aphakic
5. Any systemic disease that may affect the eye or be exaggerated by wearing contact lenses
6. Allergic reactions of ocular surfaces or adnexa that may be induced or exaggerated by wearing contact lenses or use of contact lens solutions
7. Any active corneal infection (bacterial, fungal, or viral)
8. The patient is unable to follow lens handling and wear regimen or is unable to obtain assistance to do so
9. Newly prescribed use of systemic or ocular medications for which contact lens wear could be contraindicated as determined by the investigator
10. Monocular participants (only one eye with functional vision) or participants fit with only one lens
11. Subjects with slit lamp findings greater than grade 1 (e.g., edema, infiltrates, corneal neovascularization, corneal staining, tarsal abnormalities, conjunctival, anterior segment inflammation) as per ISO 11980:2012, any previous history or signs of a contact lens related corneal inflammatory event (past corneal ulcers), or any other ocular abnormality that may contraindicate contact lens wear at the enrolment visit
12. History of herpetic keratitis, ocular surgery or irregular cornea
13. Enrolment of the family members of the investigator, family members of the investigator’s staff, or individuals living in the households of these individuals

Date of first enrolment
01/04/2024

Date of final enrolment
30/01/2025

Locations

Countries of recruitment
England

United Kingdom

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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
CooperVision

Alternative Name(s)
CooperVision, Inc., CooperVision Inc, CooperVision Inc., CooperVision, Inc

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
The plans are unknown at this stage for publication or dissemination.

Intention to publish date

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date