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Clinical investigation of soft contact lenses in children

Submission date 03/10/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 13/10/2025	**Overall study status** Completed	
Last Edited 11/03/2026	**Condition category** Eye Diseases	

Plain English summary of protocol

Background and study aims

The number of adolescents with myopia (short-sightedness) has been increasing rapidly over the last twenty years. The concern is that individuals with short-sighted eyes are more likely to develop eye diseases such as ocular pathology than individuals with healthy eyes. In order to minimize short-sightedness and potential problems later in life, various methods have been developed to reduce the effect of myopia. An example of a method used to reduce the impact of myopia is the use of special designed disposable contact lenses. This study aims to assess the short-term performance of a similar control lens versus CooperVision's test contact lenses in myopic children.

Who can participate?

Children (8 - 15 years) who have experience with soft contact lens wear, and can apply and remove soft contact lenses.

What does the study involve?

The participants will attend the visit wearing their glasses. The participant's habitual contact lenses should not be worn on the day of the visit. The visit is expected to take approximately 2.5 hours. The following procedures will be performed:

• Read and sign Informed Consent/Assent and Parental Permission/Consent. When the participant and parent have signed the appropriate forms, the participant will be considered to be enrolled in the study.
• Demographics
• Medical and ocular health history
• Contact lens and refractive history
. 1st contact lens application
- Subjective responses
- Vision
- Lens fit
. 2nd contact lens application
- Subjective responses
- Vision
- Lens fit

. Lens removal
• Review of adverse events
• Study exit.

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?
Eurolens Research, University of Manchester (UK).

When is the study starting, and how long is it expected to run for?
August 2025 to May 2026

Who is funding the study?
CooperVision International Limited (USA)

Who is the main contact?
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Additional identifiers

Integrated Research Application System (IRAS)
357884

Protocol serial number
MKTG-166

Study information

Scientific Title
Clinical performance of two myopia control contact lenses in children

Acronym
CPTMCCLC

Study objectives

The objective of this study is to assess the short-term performance of senofilcon A (control lens) versus stenfilcon A (test lens) silicone hydrogel daily disposable contact lenses in myopic children.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 14/08/2025, West Midlands - Edgbaston Research Ethics Committee (2 Redman Place, Stratford, E20 1JQ, United Kingdom; +44 20 7104 8260; edgbaston.rec@hra.nhs.uk), ref: 25/WM/0127

Primary study design
Interventional

Study design
Single-visit randomized double-masked non-dispensing study

Study type(s)
Other

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

Interventions
The study will be a randomized, double-masked, non-dispensing, prospective study involving a single visit with approximately 2.5 hours of wear, to assess the short-term performance of senofilcon A (control lens) versus stenfilcon A (test lens) contact lenses in myopic children.

The order in which the two study contact lenses will be fitted will be randomized to minimise bias. Block randomization will be computer-generated based on the maximum enrollment number. Participants will be assigned a participant ID, and this number will be linked to the randomisation assignment.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Stenfilcon A 1-day contact lenses

Primary outcome(s)
High contrast, high luminance binocular distance visual acuity measured using the Precision-Vision Chart 2425-LED-200, at the one-day single visit. The visit is expected to take approximately 2.5 hours.

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
31/05/2026

Eligibility

Key inclusion criteria
1. Age 8 to 15 years (inclusive)
2. Current wearer of spherical soft contact lenses
3. The parent or guardian understands the study and rights of the participant and is willing to sign a statement of informed consent.
4. The participant understands the study at a level appropriate for their age and is willing to sign a statement of assent.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Child

Lower age limit
8 Years

Upper age limit
15 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Previous use of myopia control contact lenses.
2. Active anterior segment infection, inflammation, or abnormality that would contraindicate contact lens wear.
3. Use of systemic or ocular medication that would contraindicate contact lens wear
4. Used gas permeable/hard contact lenses (including orthokeratology) in the previous 3 months.
5. Participation in a contact lens or lens care product trial in the previous 30 days.

Date of first enrolment
25/09/2025

Date of final enrolment
31/05/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Eurolens Research
The University of Manchester, Dover St
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Sponsor information

Organisation
CooperVision International Limited

Funder(s)

Funder type
Industry

Funder Name
CooperVision International Limited

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available