ISRCTN17872996 https://doi.org/10.1186/ISRCTN17872996

Clinical investigation of soft contact lenses in children

Submission date 03/10/2025	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol
Registration date 13/10/2025	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 13/10/2025	**Condition category** Eye Diseases	[_] Individual participant data [X] Record updated in last year

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 March 2026

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

Who is the main contact?
Jose Vega, OD, MSc, PhD, FAAO
jvega2@coopervision.com

Contact information

Type(s)
Public, Scientific

Contact name
Dr Jose Vega

Contact details
2120 West Guadalupe Road, Suite 112
Gilbert
United States of America
85233
+1-925-640-2964
jvega2@coopervision.com

Type(s)
Public, Principal investigator

Contact name
Dr Carole Maldonado-Codina

Contact details
Carys Bannister building
Division of Pharmacy and Optometry, Faculty of Biology, Medicine and Health. The University of Manchester, Dover St.
Manchester
United Kingdom
M13 9PL

+44 (0)161 306 8761
carole.m-codina@manchester.ac.uk

Type(s)
Public

Contact name
Mrs Komalpreet Kaur

Contact details
6101 Bollinger Canyon Road, Suite 500
San Ramon
United States of America
94583
+1-925-353-8425
kokaur@coopervision.com

Type(s)
Public

Contact name
Ms Archana Binod-Nair

Contact details
Delta Park, Concorde Way, Segensworth North
Fareham
United Kingdom
PO15 5RL
+44 7974858818
Archana.Binod-Nair@coopervision.co.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
357884

ClinicalTrials.gov (NCT)
Nil known

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

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

Primary study design
Interventional

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
18/03/2026

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

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
18/03/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Eurolens Research
The University of Manchester, Dover St
Manchester
United Kingdom
M13 9PL

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
The data sharing plans for the current study are unknown. The datasets generated during and/or analysed during the current study are not expected to be made available due to the confidential and proprietary nature of the clinical study.

IPD sharing plan summary
Not expected to be made available, Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes