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Clinical performance and safety of soft contact lenses in children

Submission date 03/10/2025	**Recruitment status** Not yet recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 13/10/2025	**Overall study status** Ongoing	
Last Edited 13/10/2025	**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. To minimize short-sightedness and potential problems later in life, various methods have been developed to reduce the effect of myopia. Some methods used to reduce the impact of myopia are the use of specially designed disposable soft contact lenses and spectacle lenses. This study aims to assess the performance of myopic control soft daily disposable contact lenses and spectacles in myopic children.

Who can participate?
Otherwise healthy children aged 8 to 12 years who have experience with soft contact lenses and spectacles wear. Children who can apply and remove soft contact lenses and spectacle glasses.

What does the study involve?
The participants will attend the visit wearing their glasses or contact lenses. The visits are expected to take approximately 24 weeks, including initial and follow-up visits. 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
• First 12 weeks
- Collection and fitting
- Compliance and wear assessment
- Vision
. Second 12 weeks
- Collection and fitting
- Compliance and wear assessment
- Vision

. 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?
October 2025 to October 2026

Who is funding the study?
CooperVision International Limited, USA

Who Is The Main Contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
MKTG-171

Study information

Scientific Title
Clinical investigation of myopia control contact lenses and spectacles in children

Acronym
CIMCCLSC

Study objectives

The objective of this study is to compare the clinical performance, safety, and subjective acceptance of myopia control soft contact lenses and myopia control spectacles in young myopes.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/09/2025, University Research Ethics Committee 3 (Research Governance, Ethics and Integrity, 2nd Floor Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, United Kingdom; +44 (0) 161-306-6000; urec3@manchester.ac.uk), ref: 2025-23893-4348 4

Study design
Randomized bilateral 12-week crossover study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Home, Other therapist office

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, bilateral, 12-week crossover study comparing myopic control soft daily disposable contact lenses and spectacles in myopic children.

Block randomization will be computer-generated based on maximum enrollment numbers. Participants will be assigned a participant ID, and this number will be linked to the randomization assignment. After subjects are enrolled in the study, they will be randomized into two groups (Contact Lenses and Spectacles). They will be followed at the following time points: 1, 4 and 12 weeks. After 12 weeks, they will cross over to the other treatment group (Spectacles and Contact Lenses) and will be followed up for the same period of time prior to study exit.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

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

Primary outcome measure
Intervention preference between spectacles versus contact lenses will be measured by asking subjects to provide their overall preferred intervention and the reasons for their choice using a 5-point Likert scale at the 12-week timepoint. In addition, where a participant selects the neutral option, a follow-up question will be asked to “force” them to decide. Reasons for their choice will also be collected.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/09/2025

Completion date
01/10/2026

Eligibility

Key inclusion criteria
To be enrolled, each participant shall meet the following criteria:
1. Age 8 to 12 years
2. They have no previous experience with 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
5. They are willing and able to follow the protocol

Participant type(s)
Healthy volunteer

Age group
Child

Lower age limit
8 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
55

Total final enrolment
47

Key exclusion criteria
The following are specific criteria that exclude a candidate from enrolment in this study:
1. Ocular disorder that would normally contraindicate contact lens wear
2. Corneal refractive surgery or have an irregular cornea
3. Use of systemic or ocular medication that would contraindicate contact lens wear
4. Candidate is aphakic
5. Participation in a contact lens or lens care product trial in the previous 30 days

Date of first enrolment
24/10/2025

Date of final enrolment
01/10/2026

Locations

Countries of recruitment
England

United Kingdom

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

Organisation
CooperVision International Limited

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Sponsor type
Industry

Website
https://coopervision.com/

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
Planned publication in a peer-reviewed journal

Intention to publish date
01/10/2027

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
Stored in non-publicly available repository, Not expected to be made available