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Clinical study of a range of soft contact lens brands

Submission date 09/08/2024	**Recruitment status** Recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [X] Record updated in last year
Registration date 16/08/2024	**Overall study status** Ongoing	
Last Edited 04/08/2025	**Condition category** Eye Diseases	

Plain English summary of protocol

Background and study aims
The aim of this study is to confirm the current safety and effectiveness of sphere, toric, and multifocal lenses compared to similar marketed devices and to address the long-term safety and performance of daily wear in users of these lenses. The choice of lenses was made to assess the clinical performance of the test lenses against currently marketed state-of-the-art products for the same indication.

Who can participate?
Patients aged between 8 and 75 years old who are current wearers of CE-marked CooperVision test or control lenses. Equivalent private-label contact lenses can be included in either group (for at least 6 months)

What does the study involve?
The participants will attend the clinic for one study visit wearing the study test or control lenses. The visit will be about 2 hours long during which participants will complete a questionnaire, have their vision measured, the contact lens fit evaluated, and their eyes examined. In addition, the investigator will review participant clinical notes available at the practice site to identify any adverse events associated with wearing study test or control lenses.

What are the possible benefits and risks of participating?
There may not be direct benefits to the participants, but participation may contribute to scientific information that may be used in the development of new contact lens products. The knowledge gained from this study may lead to important conclusions regarding the real-world safety and effectiveness of these lenses. The potential risks are minimal so the benefit-risk ratio is acceptable. Participants will already be routinely wearing these lenses so this is considered a non-significant risk study. Routine non-invasive procedures will be conducted in this study.

Where is the study run from?
Eurolens (UK)

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

Who is funding the study?
CooperVision Inc., Ltd (USA)

Who is the main contact?
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Contact information

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CV-23-91

Study information

Scientific Title
This study aims to assess the post-market safety and performance of a range of contact lens types

Study objectives
The objective of this post-market study is to demonstrate acceptable safety and effectiveness (performance) of a range of CooperVision soft contact lens types compared with similar marketed devices, when used in the general population.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 02/07/2024, University Research Ethics Committees (URECs) (2nd Floor, The Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, United Kingdom; +44 (0)161 306 6000; urec1@manchester.ac.uk), ref: 2024-20572-36344

Study design
Prospective single-visit open-label observational study

Primary study design
Observational

Secondary study design
Population study

Study setting(s)
Medical and other records, Optician

Study type(s)
Safety, Efficacy

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

Health condition(s) or problem(s) studied
Myopia, astigmatism, hyperopia, presbyopia

Interventions
Recruitment:
Subjects will be recruited from the site's own patient listings based in England and Scotland.

Consenting:
Informed consent shall be obtained in writing from adult subjects, as well as assent and parental permission/consent from minors and their parent or legal guardian. The process shall be performed by an appropriately trained/delegated study member and will be documented before any procedure specific to the clinical investigation is carried out. The study members will be trained in the conduct of clinical research, show willingness to follow the study protocol and will be trained in GCP and the study protocol before commencing the study.

The potential participant will attend the clinic for one study visit wearing the study test or control lenses. The visit will be about 2 hours long during which participants will be consented to participate in the study, complete a questionnaire, have their vision measured, the contact lens fit evaluated, and their eyes examined. In addition, the investigator will review participant clinical notes available at the practice site to ensure that any adverse events associated with wearing study tests or control lenses that may have occurred are identified and analysed.

Please find below a list of the contact lenses ‘or similar’ tested:
Avaira Vitality Sphere
Proclear Sphere
Biomedics 55 Asphere
Biomedics Now Sphere
Avaira Vitality Toric
Proclear Toric and Toric XR
Biomedics Toric
Proclear Multifocal and Mulitfocal XR
Proclear Multifocal Toric
Clariti 1 day Daily Disposable Sphere
Biomedics 1 Day Extra-1 Day Sphere
Proclear - 1 Day – Sphere
Live 1 day
Clariti 1 day Daily Disposable Toric
Biomedics 1 Day Toric and EXTRA Toric
Clariti 1 day Daily Disposable Multifocal
Proclear 1 Day Multifocal

The acceptance and performance of the contact lenses will be tested for efficacy as per ISO11980-2012:
1. Measurement of contact lens logMAR visual acuity
2. Subjective rating of comfort, vision and handling
3. Subjective rating of contact lens fit and contact lens surface characteristics

The performance will be tested for safety as per ISO11980-2012:
1. Identification of ocular adverse events related to contact lens wear
2. Measurement of spectacle logMAR visual acuity
3. Assessment of the ocular tissues and ratings as per ISO11980-2012 scales

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Range of soft contact lens brands

Primary outcome measure
1. Visual performance (visual acuity) measured based on high-contrast visual acuity at one timepoint
2. Incidence of contact lens-related adverse events measured using subject reports and slit lamp evaluation

Secondary outcome measures
Relationship determination between lens fit, surface measurements, and subjective scores measured using appropriate statistical modeling, slit lamp evaluation, and VAS/ISO Questionnaires at one timepoint

Overall study start date
05/12/2023

Completion date
31/10/2025

Eligibility

Key inclusion criteria
1. Age 8 to 75 years (inclusive)
2. They understand their rights as a research subject and are willing to sign a Statement of Informed Consent
3. Current wearer (for at least 6 months) of CE-marked CooperVision test or control lenses. Equivalent private-label contact lenses can be included in either group

Participant type(s)
Healthy volunteer

Age group
Mixed

Lower age limit

8 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
700

Key exclusion criteria
Participation in a contact lens or contact lens care product clinical trial within the previous 30 days

Date of first enrolment
01/08/2024

Date of final enrolment
30/11/2025

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
Eurolens Research
The University of Manchester
Oxford Road
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Sponsor information

Organisation
CooperVision Inc Ltd

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Sponsor type
Industry

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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
Due to the confidential and proprietary nature of the clinical study, any presentation and/or publication, including but not limited to those made at scientific meetings, in-house, in peer-reviewed journals, professional publications, etc, cannot be published without the written consent of the Sponsor. Details of the publication procedures are in the clinical study agreement.

Intention to publish date
01/07/2025

Individual participant data (IPD) sharing plan

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. Details of the publication procedures are in the clinical study agreement.

IPD sharing plan summary

Not expected to be made available