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Early presbyopia population characterisation

Submission date 17/07/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 29/07/2025	**Overall study status** Completed	
Last Edited 29/07/2025	**Condition category** Eye Diseases	

Plain English summary of protocol

Background and study aims
The onset of presbyopia is a continuous physiological phenomenon. Typically, the timing of the initial correction of presbyopia, whether with contact lenses or spectacles, is when patients report near vision-associated symptoms. This study aims to characterise the early presbyopic population with a view to identify factors likely to contribute to the difficulty in transferring from single vision to multifocal vision correction and to differentiate between asymptomatic adaptors during the period preceding the use of a multifocal correction.

Who can participate?
Early presbyopes aged between 40 to 50 years old with single vision correction or no vision correction.

What does the study involve?
The study involves attending one study visit and completing a set of remote questionnaires in 10 days following the study visit.

What are the possible benefits and risks?
The study results will contribute to additional information on early presbyopia.

No risks given at registration

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

When is the study starting and how long is it expected to run for?
March 2025 to September 2025

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

Who is the main contact?
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Contact information

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Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
354245

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CV24-52

Study information

Scientific Title
Early presbyopia program phase 1 population characterisation

Study objectives

The study will be an observational study to increase knowledge on early presbyopia, therefore, no specific hypothesis will be tested, however, the study results will make it possible to develop specific hypotheses to be tested to improve the management of early presbyopia.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 30/05/2025, London-Brent Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)2071048128, 207 104 8117, 2071048131; brent.rec@hra.nhs.uk), ref: 25/PR/0578

Study design
Single-visit in-clinic prospective observational study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Early presbyopia

Interventions
The study will be a single-visit, in-clinic, prospective observational study followed by three remote time-controlled questionnaires implemented on three different days within the following 10-day period.

The participants will attend the clinic wearing their habitual visual correction and will bring their electronic devices (e.g. laptops, tablets, electronic books, smartphones) to quantify their near environment needs. The potential participants will be screened and enrolled on the study. Once enrolled, the participant will complete a set of questionnaires, and then the investigator will carry out a set of non-invasive clinical measurements. At the end of the visit, a remote electronic controlled questionnaire will be set up.
The participants will complete three remote electronic questionnaires each on three different days within the following 10-day period.

Intervention Type
Other

Primary outcome(s)
1. Optical and visual characteristics of the early presbyopic population measured using time-controlled visual acuity at two points during the study visit
2. Identify differentiating factors between symptomatic and asymptomatic early presbyopes measured using subjective questionnaires during the study visit and remotely after the study visit

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

Completion date
30/09/2025

Eligibility

Key inclusion criteria
The entry criteria will be:
1. Age 40 to 50 years
2. Vision correction:
2.1. Distance Vision Correction only
2.1.1. Single vision distance spectacles
2.1.2. Single vision distance contact lenses
2.1.3. No vision correction
3. Spectacle refraction:
3.1. Distance: Sphere: -6.00D to + 3.00D
3.2. Astigmatism: 0.00D to -2.50
4. Best corrected distance visual acuity of at least 20/25 in each eye

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
40 years

Upper age limit
50 years

Sex
All

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 that would contraindicate contact lens wear
3. Corneal hypoesthesia (reduced corneal sensitivity), if not aphakic
4. Severe insufficiency of lacrimal secretion (dry eyes)
5. Any systemic disease that may affect the eye or may be exaggerated by wearing contact lenses (e.g. acne and eczema)
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, protozoal or viral)
8. Newly prescribed (within the past 30 days) use of some systemic medications (such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, stimulants, anti-depressants, anti-psychotics, oral contraceptives) or new prescription eyedrops which is not

rewetting/lubricating eyedrops for which contact lens wear could be contraindicated as determined by the investigator
9. Monocular participants (only one eye with functional vision) or participants fit with only one contact lens
10. Subjects with slit lamp findings greater than grade 1 (e.g. edema, infiltrates, corneal neovascularization, corneal staining, tarsal abnormalities, conjunctival, anterior segment inflammation) as recorded during the clinical visit, 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
11. History of corneal refractive surgery
12. 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
05/06/2025

Date of final enrolment
30/09/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Ocular Technology Group International
66 Buckingham Gate
London
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Sponsor information

Organisation
CooperVision International Limited

Funder(s)

Funder type
Industry

Funder Name
CooperVision

Results and Publications

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