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Post-market clinical follow-up for stenfilcon A sphere and toric lenses

Submission date 13/11/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 26/03/2024	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 15/07/2025	**Condition category** Eye Diseases	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
The justification for this study is to confirm the current safety and efficacy of the lens as compared to similar marketed devices and to address long-term safety and performance in users of the lens. The choice of comparator devices was made to assess the clinical performance of the Test lens 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 the Stenofilcon A sphere, toric or multifocal contact lens or similar marketed soft contact lens

What does the study involve?
A single-visit, observational study design has been chosen to reduce the burden on patients and doctors using the device, while assessing outcomes in a real-world environment.

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, and 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.

What are the possible benefits and risks of participating?
Potential benefits:
There may not be direct benefits to the subjects in this study, however, participation in the study may contribute to scientific information that may be used in the development of new contact lens products.

Potential risks:
The knowledge gained from this study may lead to important conclusions regarding the real-world safety and efficacy of this device. The potential risks for participating in this study are minimal, therefore the benefit-risk ratio is acceptable.
Participants will already be routinely wearing these lenses, and therefore this is considered a non-significant risk study. Routine, non-invasive procedures will be conducted in this study.

Where is the study run from?
Sierra Clinical Services (USA)

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

Who is funding the study?
Cooper Vision (USA)

Who is the main contact?
1. Shawna Bryant (Clinical Research Associate), sBryant3@coopervision.co.uk
2. Kathryn Richdale (Clinical Research Fellow), krichdale@coopervision.com

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
336756

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 336756

Study information

Scientific Title
This study aims to assess post-market safety and performance of stenfilcon A sphere, toric and multifocal contact lenses

Acronym
CV-23-68

Study objectives
Current study hypothesis as of 07/03/2025:
The objective of this post-marketing study is to demonstrate acceptable safety and effectiveness (performance) of Stenfilcon A Sphere, Toric and Multifocal lenses compared with similar marketed state-of-the-art devices when used in the general population.

Previous study hypothesis:
The objective of this post-marketing study is to demonstrate acceptable safety and effectiveness (performance) of Stenfilcon A Sphere & Toric lenses compared with similar marketed state-of-the-art devices when used in the general population.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 27/02/2024, South Central - Oxford A Research Ethics Committee (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, United Kingdom; +44 (0)207 1048171, +44 (0)207 104 8141, +44 (0)207 104 8272; oxforda.rec@hra.nhs.uk), ref: 24/SC/0070 - Protocol V1.0

2. Approved 18/02/2025, South Central Oxford A Research Ethics Committee (2 The Square, Bristol, BS1 6PN, United Kingdom; -; oxforda.rec@hra.nhs.uk), ref: 24/SC/0070 - Protocol V2.0

Study design
Prospective single-visit open-label observational study

Primary study design
Observational

Secondary study design
Population study

Study setting(s)
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

Interventions
The potential participant will attend the clinic for one study visit wearing the study contact lenses and having worn the study contact lenses for at least 3 hours that day. 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 they identify any adverse event associated with wearing Comfilcon A contact lenses that may have occurred are identified and analysed.

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 [3]:
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)
Stenofilcon A sphere, toric, multifocal contact lens

Primary outcome measure
1. Visual performance measured using a visual acuity chart at the single study visit
2. Incidence of contact lens-related adverse events measured using a report of contact lens related adverse events in the past 12 months at the single study visit

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
17/08/2023

Completion date
31/07/2025

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 07/03/2025:
1. Aged 8 to 75 years old (inclusive)
2. Current wearer of the Stenfilcon A Sphere, Toric or Multifocal contact lens

Previous participant inclusion criteria:
1. Aged 8 to 75 years old (inclusive)
2. Current wearer of the Stenfilcon A Sphere or Toric contact lens

Participant type(s)
Healthy volunteer

Age group
Mixed

Lower age limit
8 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
135

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

Date of first enrolment
01/04/2024

Date of final enrolment
30/06/2025

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre

Peter Ivans Eye Care
72 Drymen Road
Bearsden
Glasgow
United Kingdom
G61 2RH

Study participating centre
Bbr Optometry Ltd
Marbury House
38 St. Owen Street
Hereford
United Kingdom
HR1 2PR

Study participating centre
Leightons
5 The Broadway
St Albans
United Kingdom
AL1 3LH

Study participating centre
Coleman Opticians
7-11 St. Augustines Street
Norwich
United Kingdom
NR3 3DH

Sponsor information

Organisation
CooperVision

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Sponsor type
Industry

Website
https://coopervision.com/

Funder(s)

Funder type
Industry

Funder Name
CooperVision

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-review 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
30/06/2025

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