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Contact lens safety and performance study

Submission date
29/08/2023

Recruitment status
No longer recruiting

Registration date
30/08/2023

Overall study status
Completed

Last Edited
30/08/2023

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Comfilcon A contact lenses are CE marked and have been on the European and UK markets under the name of Biofinity® or an alternate private label. Comfilcon A contact lenses are CE-marked for both daily and overnight wear of up to 7 days for use by children and adults. The intent of this study is to collect safety and performance data in current Biofinity wearers as post-market clinical follow-up and also collect data on long-term wearers in a real-world setting. The study is an observational study of long-term wearers of comfilcon A contact lenses with at least 12 months of wear. Potential participants will be identified in practices in London and the southeast who currently fit Comfilcon A contact lenses. The practices will make the initial contact with potential participants and if interested and agreeable they will send contact information to Ocular Technology Group – International (OTG-i). OTG-i will give potential participants greater details of the study and schedule the study visit if it is the wish of the potential participant.

Who can participate:
Contact lens wearers aged 8-75 years

What does the study involve?
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.

What are the possible benefits and risks of participating?
There might not be direct benefits to the participants in this study. However, participation in the study will contribute to added information on the performance and safety of the comfilcon A family of contact lenses used by a large number of contact lens wearers as their modality of vision correction.
No significant risk is associated with taking part in the study. All the assessments are routine

clinical procedures, and none present any increased risks to participants compared with normal clinical routine. The study is an observation study of the participants wearing their habitual contact lenses during a single clinic visit.

Where is the study run from?
Ocular Technology Group International (UK)

When is the study starting and how long is it expected to run for?
November 2022 to August 2025

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

Who is the main contact?
Deborah Moore, DMoore@otg.co.uk

Contact information

Type(s)
Public

Contact name
Miss Deborah Moore

Contact details
OTGi
66 Buckingham Gate
London
United Kingdom
SW1E 6AU
+44 (0)207 222 4224
dmoore@otg.co.uk

Additional identifiers

Integrated Research Application System (IRAS)
327576

Protocol serial number
ID23-05 CV23-24

Study information

Scientific Title
Comfilcon A contact lenses medical device regulation study

Study objectives
The primary efficacy hypothesis is that the binocular visual performance of comfilcon A contact lenses is non-inferior to that of the equivalent spectacle correction.

The primary safety hypothesis is that the frequency of serious and significant adverse events is non-inferior (not greater) than the accepted frequency for extended-wear contact lenses (8.3% overall).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 09/06/2023, London - Riverside Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)20 7104 8150; riverside.rec@hra.nhs.uk), ref: 23/PR/0414

Primary study design
Observational

Study design
Single-arm observational population study

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Presbyopia, myopia, hyperopia, astigmatism

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

Population profiling will use the following procedures:
1. Demographics and medical and ocular history
2. Contact lens-wearing characteristics
3. Manifest spectacle refraction (sphero-cylinder)
4. Keratometry

Intervention Type

Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Comfilcon A Contact Lenses

Primary outcome(s)
logMAR photopic (200 cd/m2) high contrast (>90%) visual acuity at distance (400 cm) and near (40 cm) measured to the nearest letter, measured at a single timepoint during the visit

Key secondary outcome(s)
1. Comfort recorded on a six-point scale, measured at a single timepoint during the visit
2. Vision recorded on a six-point scale, measured at a single timepoint during the visit
3. Handling recorded on a six-point scale, measured at a single timepoint during the visit

Completion date
15/08/2025

Eligibility

Key inclusion criteria
1. Contact lens wearers using comfilcon A family of contact lenses comprising Biofinity® and private label, sphere, toric, multifocal, toric multifocal
2. Age 8-75 years
3. Current wearer of one of the above contact lens types for at least 12 months managed by referring practice
4. At least occasional overnight wear in the last 12 months
5. Be willing and able to adhere to the instructions set in the clinical protocol and maintain the appointment scheduled at OTG-i

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
8 Years

Upper age limit
75 Years

Sex
All

Key exclusion criteria
Current participation of the subject in a contact lens or contact lens care product clinical trial

Date of first enrolment
18/08/2023

Date of final enrolment
01/08/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Ocular Technology Group International
66 Buckingham Gate
London
United Kingdom
SW1E 6AU

Sponsor information

Organisation
Cooper Vision International Ltd

Funder(s)

Funder type
Industry

Funder Name
Cooper Vision International Ltd

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