ISRCTN16851376 https://doi.org/10.1186/ISRCTN16851376

Clinical evaluation of scleral contact lenses

Submission date
22/06/2022

Recruitment status
No longer recruiting

Registration date
07/07/2022

Overall study status
Completed

Last Edited
25/04/2023

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
The aim of this study is to find out whether changing to a different type of scleral contact lens (different overall sagittal height) affects contact lens centration.

Who can participate?
Adults who are least 40 years old, who have healthy eyes and who wear multifocal contact lenses.

What does the study involve?
Phase 1 involves two study visits in which participants will be fitted with two different pairs of contact lenses at each visit. Each pair will be worn for about an hour and a half and in this time, video recordings and photos of the lens fit will be taken by a member of the study staff. The second visit will be at least 3 days after the first visit.
Phase 2 will involve participants returning to the clinic to wear a fifth pair of contact lenses and the same routine will be followed - they will wear the contact lenses for about an hour and a half and in this time, video recordings and photos of the lens fit will be taken by a member of the study staff.

What are the possible benefits and risks of participating?
The participants are current contact lens wearers and they will use three currently marketed contact lenses under the control of the investigator. The risks to the participant are no greater than wearing their own contact lenses. The risks will be further minimised by the fact that the contact lenses will only be worn in the clinic under the supervision of the investigators. The possible benefit to the participant will be to try different contact lenses with different levels of comfort that they could eventually purchase from their own practitioner.

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?
June 2022 to March 2023

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
Ms Deborah Moore

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
315747

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CV22-19 ID22-21, IRAS 315747

Study information

Scientific Title
Non-dispensing clinical evaluation of customised OneFit MED scleral contact lenses

Study objectives
The primary hypothesis to be tested will be that changing the scleral contact lens overall sagittal height will affect contact lens centration.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 23/05/2022, South Central - Oxford A Research Ethics Committee (Ground Floor, Temple Quay House, 2 the Square, Bristol, BS1 6PN, UK; +44 (0)2071048290; oxforda.rec@hra.nhs.uk), ref: 22/SC/0171

Study design
Single-centre non-randomized sequential study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Presbyopia

Interventions
Each participant will wear all the study contact lenses in a sequential fashion for about 1 hour and a half each. During each period of wear, contact lens fitting video recordings and photos will be taken. These will then be analysed post hoc.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
OneFit MED Scleral Lens

Primary outcome(s)
Contact lens centration in primary and down gaze measured in mm after 40 minutes of wear

Key secondary outcome(s))
Corneal clearance measured in mm after 40 minutes of wear

Completion date
01/03/2023

Eligibility

Key inclusion criteria
1. 40 or more years of age
2. Have read and understood the Participant Information Sheet in English
3. Have read, signed and dated the Informed Consent
4. Current multifocal contact lens wearer
5. Spectacle refraction:
5.1. Distance: Sphere: -6.00D to + 4.00DS
5.2. Astigmatism: -0.00DC to -1.50DC in each eye

5.3. Near Addition: +0.75D to +2.50D
6. Best corrected visual acuity of at least 20/25 in each eye
7. Have normal eyes with the exception of the need for visual correction
8. Be willing and able to adhere to the instructions set in the clinical protocol and maintain the appointment schedule

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Ocular anterior segment infection, inflammation, abnormality, or active disease that would contraindicate contact lens wear
2. Use of systemic or ocular medications for which contact lens wear could be contraindicated as determined by the investigator
3. Monocular participants (only one eye with functional vision) or participants fit with only one lens
4. Any moderate or severe ocular condition observed during the slit lamp examination at the enrolment visit
5. History of herpetic keratitis, ocular surgery or irregular cornea
6. Known pregnancy or lactation during the study period
7. Enrolment of the investigator or his/her staff, 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
06/07/2022

Date of final enrolment
01/12/2022

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
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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results	version 1.0	24/04/2023	25/04/2023	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes