ISRCTN90702227 https://doi.org/10.1186/ISRCTN90702227

Phase I trial: Ocular Technology Group International

Submission date	Recruitment status	[ ] Prospectively registered
07/08/2023	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
15/08/2023	Deferred	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/08/2023	Other	[ ] Record updated in last year

Plain English summary of protocol
The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
326886

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 326886, ID23-11A CV23-07

Study information

Scientific Title
Phase I trial: Ocular Technology Group International
[The full scientific title will be published within 30 months after the end of the trial]

Study objectives
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Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 22/05/2023, South East Scotland Research Ethics Committee 02 (2nd Floor, Waverley Gate 2-4 Waterloo Place., Edinburgh, EH1 3EG, United Kingdom; 01315369000; ruth.fraser4@nhslothian.scot.nhs.uk), ref: 23/SS/0051

Study design
Non dispensing prospective, contralateral study design in 20 participants

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format.

Health condition(s) or problem(s) studied
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Interventions
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Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Phase I

Drug/device/biological/vaccine name(s)
The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

Primary outcome measure
The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

Secondary outcome measures
The Health Research Authority (HRA) has approved deferral of publication of the full details of the trial. The full details will be added to the study record within 30 months after the trial has ended.

Overall study start date
01/10/2022

Completion date
31/12/2023

Eligibility

Key inclusion criteria
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Participant type(s)
Healthy volunteer

Age group
Mixed

Lower age limit
40 Years

Upper age limit
90 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
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Date of first enrolment
30/06/2023

Date of final enrolment
01/09/2023

Locations

Countries of recruitment
England

United Kingdom

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

Organisation
CooperVision International Limited

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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Cooper Vision International Ltd

Results and Publications

Publication and dissemination plan
Full trial details will be published up to 30 months after the end of the trial. Publication of some trial details is deferred because of the high commercial sensitivity of this phase I study and the negligible benefit to the public of phase I information. Results will be posted on or after the date of publication of full trial details.

Intention to publish date
03/02/2026

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study are not expected to be made available because of their high commercial sensitivity and the negligible benefit to the public of publication of results of non-therapeutic clinical trials.

IPD sharing plan summary
Not expected to be made available