ISRCTN66819383 https://doi.org/10.1186/ISRCTN66819383

Phase I trial: Ocular Technology Group International CV23-08

Submission date 25/01/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 26/01/2024	**Overall study status** Deferred	
Last Edited 26/01/2024	**Condition category** Other	

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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Scientific, Principal investigator

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
327300

Protocol serial number
CV23-08, IRAS 327300

Study information

Scientific Title
Phase I trial: Ocular Technology Group International CV23-08 [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 2 (2nd Floor, Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG, United Kingdom; +44 (0)131 536 9000; ruth.fraser4@nhslothian.sct.nhs.uk), ref: 23/SS/0052

Study design
Non-dispensing prospective single-arm study

Primary study design
Interventional

Study type(s)
Other

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

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Intervention Type
Device

Phase
Phase I

Drug/device/biological/vaccine name(s)
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Primary outcome(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.

Key secondary outcome(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.

Completion date
01/02/2025

Eligibility

Key inclusion criteria
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Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
40 years

Upper age limit
90 years

Sex
All

Key exclusion criteria
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Date of first enrolment
01/02/2024

Date of final enrolment
01/02/2025

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
CooperVision International Ltd

Funder(s)

Funder type
Industry

Funder Name
CooperVision

Alternative Name(s)

CooperVision, Inc., CooperVision Inc, CooperVision Inc., CooperVision, Inc

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

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