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

Integrated Research Application System (IRAS)
326886

Protocol serial number
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

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
31/12/2023

Eligibility

Key inclusion criteria
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Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
40 years

Upper age limit
90 years

Sex
All

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
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
Cooper Vision International Ltd

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