

Phase I trial: Ocular Technology Group International CV23-08

Submission date 25/01/2024	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/01/2024	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 26/01/2024	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Type(s)

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

ClinicalTrials.gov (NCT)
Nil known

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)

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Key secondary outcome(s)

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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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes