

Phase I trial: Ocular Technology Group International

Submission date 07/08/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 15/08/2023	Overall study status Deferred	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 15/08/2023	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

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

326886

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

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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)

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Key secondary outcome(s)

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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