

# Phase I trial: Ocular Technology Group International CV23-38

<b>Submission date</b> 20/11/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 26/11/2024	<b>Overall study status</b> Deferred	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 26/11/2024	<b>Condition category</b> Eye Diseases	<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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## Additional identifiers

**Integrated Research Application System (IRAS)**  
342156

**Protocol serial number**  
ID23-37 CV23-38

## Study information

### Scientific Title

Phase I trial: Ocular Technology Group International CV23-38  
[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 13/06/2024, South East Scotland Research Ethics Committee 02 (2nd Floor, Waverley Gate 2-4 Waterloo Place, Edinburgh, EH1 3EG, United Kingdom; +44 131 5369000; ruth.fraser4@nhslothian.scot.nhs.uk), ref: 24/SS/0049

### Study design

Non dispensing bilateral randomized 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**

29/10/2024

**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

**Total final enrolment**

11

## Key exclusion criteria

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## Date of first enrolment

01/08/2024

## Date of final enrolment

25/10/2024

## 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

CooperVision 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