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

### 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
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.

### 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
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.

### Intervention Type
Device

### Phase
Phase I

### Drug/device/biological/vaccine name(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.

### 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
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.

### 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

## 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 |