

Phase I trial: Ocular Technology Group International CV23-38

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

EudraCT/CTIS number
Nil known

IRAS number
342156

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

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Interventions

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Intervention Type

Device

Pharmaceutical study type(s)

Not Applicable

Phase

Phase I

Drug/device/biological/vaccine name(s)

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Primary outcome measure

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Secondary outcome measures

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.

Overall study start date

13/06/2024

Completion date

29/10/2024

Eligibility**Key inclusion criteria**

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Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

40 Years

Upper age limit

90 Years

Sex

Both

Target number of participants

Up to 20

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**

England

United Kingdom

Study participating centre

Ocular Technology Group International

66 Buckingham Gate

LONDON

United Kingdom

SW1E 6AU

Sponsor information

Organisation

CooperVision International Limited

Sponsor details

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Pleasanton

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+1-925-251-6682

PLazon@coopervision.com

Sponsor type

Industry

Funder(s)

Funder type

Industry

Funder Name

CooperVision International Ltd.

Results and Publications

Publication and dissemination plan

Full trial details will be published up to 30 months after the end of the trial. Publication of some trial details is deferred because of the high commercial sensitivity of this phase I study and the negligible benefit to the public of phase I information. Results will be posted on or after the date of publication of full trial details.

Intention to publish date

31/12/2030

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