ISRCTN66819383 https://doi.org/10.1186/ISRCTN66819383

Phase I trial: Ocular Technology Group International CV23-08

Submission date 25/01/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 26/01/2024	**Overall study status** Deferred	
Last Edited 26/01/2024	**Condition category** Other	

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

Contact name
Dr Michel Guillon

Contact details
66 Buckingham Gate
London
United Kingdom
SW1E 6AU
+44 (0)207 222 4224
mguillon@otg.co.uk

Type(s)
Public

Contact name
Miss Deborah Moore

Contact details
66 Buckingham Gate
London
United Kingdom
SW1E 6AU

+44 (0)207 222 4224
dmoore@otg.co.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
327300

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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
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 trail has ended.

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

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format

Health condition(s) or problem(s) studied
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.

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

Pharmaceutical study type(s)
Not Applicable

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 measure
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.

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
01/02/2023

Completion date
01/02/2025

Eligibility

Key inclusion 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.

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
40 Years

Upper age limit
90 Years

Sex
Both

Target number of participants
40

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
01/02/2024

Date of final enrolment
01/02/2025

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 Ltd

Sponsor details
Delta Park
Concorde Way
Segensworth North
Fareham
England
United Kingdom
PO15 5RL
+1 (0)925 251 6682
plazon@coopervision.com

Sponsor type
Industry

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

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
01/02/2027

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