

ACUVUE® OASYS MAX 1-day dispensing study

Submission date 15/07/2026	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 15/07/2026	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 15/07/2026	Condition category Eye Diseases	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

The rationale for the current study is to produce a detailed characterization of the contact lens design acceptance and performance

Who can participate?

Soft contact lens wearers from 40 years and older can participate.

What does the study involve?

The participants will attend the clinic for two study visits :

During the first visit the participant will be fitted with the study contact lenses. a set which visual measurements and questionnaires will be carried out. at the end the visit 1 the participant will be dispensed with the study contact lenses to wear for 8 to 12 days and a follow up visit will scheduled

At visit 2 visual performance comfort and the vision satisfaction will be assessed by the investigators.

What are the possible benefits and risks of participating?

Where is the study run from?

Ocular Technology Group International, London.

When is the study starting and how long is it expected to run for?

This study will start in July 2026 and run for 12 months.

Who is funding the study?

CooperVision International Limited.

Who is the main contact?

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Contact information

Type(s)

Public

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Additional identifiers

Integrated Research Application System (IRAS)

373194

Protocol number

CV26-31

Study information**Scientific Title**

ACUVUE® OASYS MAX 1-day multifocal for astigmatism dispensing study

Study objectives

The study objective is to evaluate the performance and the acceptance of the study contact lenses

Ethics approval required

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Ethics approval(s)

Approved 06/07/2026, North West - Preston Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; Not available; preston.rec@hra.nhs.uk), ref: 26/NW/0191

Primary study design

Interventional

Allocation

N/A: single arm study

Masking

Open (masking not used)

Control

Uncontrolled

Assignment

Single

Purpose

Basic science

Study type(s)**Health condition(s) or problem(s) studied**

Presbyopia & Astigmatism

Interventions

The participants will attend the clinic for two study visits :

At the first visit the participant will be fitted with the study contact lenses. A set of visual measurements and questionnaires will be carried out. At the end the visit 1 the participant will be dispensed with the study contact lenses to wear for 8 to 12 days and a follow up visit will be scheduled.

At visit 2 visual performance comfort and the vision satisfaction will be assessed by the investigators.

Intervention Type

Device

Phase

Phase IV

Drug/device/biological/vaccine name(s)

ACUVUE® OASYS MAX 1-Day MULTIFOCAL for ASTIGMATISM

Primary outcome(s)

1. Overall vision satisfaction at the completion of the wearing period measured using a 100-point Visual Analogue Scale (VAS) at visit 2

Key secondary outcome(s)

Completion date

01/09/2026

Eligibility

Key inclusion criteria

1. Age 40 years or greater
2. Have read and understood the participant Information Sheet
3. Have read, signed and dated the Informed Consent
4. Best corrected visual acuity of at least 20/25 in each eye
5. Have normal eyes with the exception of the need for visual correction
6. Current soft contact lenses wearer
7. Spectacle refraction:
 - 7.1 Distance Sphere: -6.00 D to -0.50 D
 - 7.2 Astigmatism (Cylinder): -0.75 D to -1.75 D
 - 7.3 Axis: 10° , 20° , 30° , 70° , 80° , 90° , 100° , 110° , 150° , 160° , 170° , 180°
 - 7.4 Near Addition: $+0.75$ D to $+2.50$ D
8. Be willing and able to adhere to the instructions set in the clinical protocol and maintain the appointment schedule

Healthy volunteers allowed

Yes

Age group

Mixed

Lower age limit

40 Years

Upper age limit

85 Years

Sex

All

Total final enrolment

0

Key exclusion criteria

1. Ocular anterior segment infection, inflammation, abnormality, or active disease that would contraindicate contact lens wear
2. Newly prescribed (within the past 30 days) use of some systemic medications (such as antihistamines, decongestants, diuretics, muscle relaxants, tranquilizers, stimulants, antidepressants, anti-psychotics, oral contraceptives) or new prescription eyedrops which is not rewetting/lubricating eyedrops for which contact lens wear could be contraindicated as determined by the investigator
3. Monocular participants (only one eye with functional vision) or participants fit with only one lens

lens

4. Any moderate or severe ocular condition observed during the slit-lamp examination at the enrolment visit

5. History of herpetic keratitis, ocular surgery or irregular cornea

6. Known pregnancy or lactation during the study period

7. Enrolment of the investigator or his/her staff, family members of the investigator, family members of the investigator's staff, or individuals living in the households of these individuals

Date of first enrolment

17/07/2026

Date of final enrolment

30/08/2026

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Optometric Technology Group Ltd

66 Buckingham Gate

London

England

SW1E 6AU

Sponsor information

Organisation

CooperVision International Limited

Funder(s)

Funder type

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

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Data sharing statement to be made available at a later date