

Clinical Evaluation of DP037, for contact lens users

Submission date 04/07/2012	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/07/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 12/01/2018	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The standard method of cleaning rigid gas permeable (RGP) contact lenses is to soak the lenses in a solution containing chemical disinfectant. Some disinfectants are highly effective against microorganisms but users are required to neutralize the solutions before wearing the lenses. However, disinfectant that is too strong may be toxic to the eye. The contact lens care product DP037 (Menicon) is a multi-purpose solution applicable to all RGP contact lenses and is intended for washing, disinfection, rinsing and storage of contact lenses. The purpose of this study is to compare DP037 (test solution) with another solution on the market (control solution).

Who can participate?

The participants involved in this study will be at least 18 years of age and selected on the basis of having healthy eyes, except for the need for vision correction. The participants need to have worn RGP contact lenses for at least 3 months prior to the study.

What does the study involve?

Participants randomly assigned to use either the test or the control solution for 3 months and given a new set of RGP contact lenses during the study. The participants will be required to attend for a maximum of five study visits. During those visits their eyes will be examined and asked to complete questionnaires.

What are the possible benefits and risks of participating?

The participants could potentially experience side effects or sensitivity to the ingredients in the lens care solution. Adverse reactions associated with RGP lenses and their care products include: eyes stinging, burning or itching (irritation), excessive watering (tearing) of the eyes, unusual eye secretions, redness of the eyes, reduced sharpness of vision (visual acuity), blurred vision, rainbows or halos around objects, sensitivity to light (photophobia), dry eyes. As with any new product, problems may occur which are currently unforeseeable.

Where is the study run from?

The study will be carried out in five sites in the UK.

When is study starting and how long is it expected to run for?
February 2012 to April 2013.

Who is funding the study?
Menicon Co., Ltd (Japan).

Who is the main contact?
Mr Hideto Ogawa
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Contact information

Type(s)
Scientific

Contact name
Mr Hideto Ogawa

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Additional identifiers

Protocol serial number
MENP-2901

Study information

Scientific Title
Three-month clinical evaluation of DP037, a multipurpose solution for Rigid Gas Permeable (RGP) lenses

Study objectives
The DP037 RGP multipurpose solution is substantially equivalent to the another RGP solution when used with a rub and rinse regimen.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. UK: NRES committee South East Coast - Brighton and Sussex, 27/07/2012, ref: 12/LO/1035
2. UK: MHRA, 09/08/2012, ref: CI/2012/0027. Amendments approved on 23/08/2012.

Study design

Three-month double-masked bilateral randomised comparative study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Contact lens wear

Interventions

Subjects will be randomly assigned to use either the test or the control solution and clinically evaluated at the initial baseline visit (Visit 1), then after 1 week, 1 month, and 3 months of lens wear.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Comfort
2. Comfortable wearing time
3. Lens surface
4. Slit lamp findings for 3 months

Key secondary outcome(s))

No secondary outcome measures

Completion date

09/04/2013

Eligibility

Key inclusion criteria

1. Be a currently adapted RGP contact lens wearer (>3 months of lens wear)
2. Wearing their habitual RGP contact lenses to baseline visit
3. Be at least 18 years of age
4. Have corneal astigmatism less than or equal to 3.00D
5. Have clear corneas and be free of any anterior segment disorders
6. Be correctable through spherocylindrical refraction to 6/12 (20/40) or better in each eye
7. Spherical spectacle prescriptions between +6.00D and -10.00D (inclusive)
8. Require visual correction in both eyes (monovision allowed, but not monofit)
9. Have normal eyes with no evidence of abnormality or disease. For the purposes of this study a normal eye is defined as one having:
 - 9.1. No amblyopia
 - 9.2. No strabismus
 - 9.3. No evidence of lid abnormality or infection

- 9.4. No conjunctival abnormality or infection that would contraindicate contact lens wear
- 9.5. No clinically significant slit lamp findings (i.e. corneal staining, stromal oedema, staining, scarring, vascularisation, infiltrates or abnormal opacities)
- 9.6. No other active ocular disease

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Under 18 years of age
2. Wear toric or multifocal RGP designs
3. Previously shown a sensitivity to any of the study solutions components
4. Any systemic or ocular disease or allergies affecting ocular health
5. Using systemic or topical medications that will in the investigator's opinion affect ocular physiology or lens performance
6. Clinically significant (no less than Grade 3) corneal staining, corneal stromal oedema, corneal vascularisation, tarsal abnormalities, bulbar hyperaemia, limbal hyperaemia, or any other abnormality of the cornea that would contraindicate contact lens wear
7. Any corneal infiltrates or any corneal scarring or neovascularisation within the central 5mm of the cornea
8. Keratoconus or other corneal irregularity
9. Aphakia or amblyopia
10. Subjects who have undergone corneal refractive surgery or any anterior segment surgery
11. Abnormal lacrimal secretions
12. Has diabetes
13. Known/reported infectious disease (e.g., hepatitis, tuberculosis) or an immunosuppressive disease [e.g. Human immunodeficiency virus (HIV)]
14. History of chronic eye disease [e.g. glaucoma or Age-related macular degeneration (ARMD)]
15. Pregnant or lactating or planning a pregnancy at the time of enrolment
16. Participation in any concurrent clinical trial or in last 30 days

Date of first enrolment

25/08/2012

Date of final enrolment

27/11/2012

Locations

Countries of recruitment

United Kingdom

Japan

Study participating centre

Menicon Co. Ltd

Nagoya

Japan

460-0006

Sponsor information

Organisation

Menicon Co. Ltd (Japan)

ROR

<https://ror.org/032a2g603>

Funder(s)

Funder type

Industry

Funder Name

Menicon Co. Ltd (Japan)

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Not provided at time of registration