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Clinical Evaluation of DP037, for contact lens users

Submission date 04/07/2012	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 13/07/2012	**Overall study status** Completed	
Last Edited 12/01/2018	**Condition category** Eye Diseases	

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

Contact details
Menicon Co. Ltd
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
No secondary outcome measures

Overall study start date
18/02/2012

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Approximately 60 subjects (approximately 40 subjects will be assigned to use the test solution and 20 subjects to use the control solution).

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
Japan

United Kingdom

Study participating centre
Menicon Co. Ltd
Nagoya
Japan
460-0006

Sponsor information

Organisation
Menicon Co. Ltd (Japan)

Sponsor details
3-21-19
Aoi, Naka-ku
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Japan
460-0006

Sponsor type
Industry

Website

http://www.menicon.com/

ROR
https://ror.org/032a2g603

Funder(s)

Funder type
Industry

Funder Name
Menicon Co. Ltd (Japan)

Results and Publications

Publication and dissemination plan
There are no specific plans for publication or dissemination of the study results.

Intention to publish date

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