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Ocular effect of TRPM8 agonist in patients with dry eye disease

Submission date	Recruitment status	[_] Prospectively registered
17/03/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/03/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/06/2020	Eye Diseases	

Plain English summary of protocol

Background and study aims
Dry eye disease occurs when the eyes do not make enough tears or the tears evaporate too quickly, leading to the eyes drying out and becoming inflamed (red and swollen) and irritated. Our aim is to study the effect of topical administration of TRPM8 agonist in patients with mild to moderate dry eye disease.

Who can participate?
Patients with mild to moderate dry eye.

What does the study involve?
60 patients are randomly allocated to be treated with either TRPM8 agonist dissolved in distilled water, or distilled water only. Study medications will be topically applied twice on the upper eyelid. The severity of dry eye symptoms will be evaluated before and 1 hour after application.

What are the possible benefits and risks of participating?
There are no benefits and risks involved in this study.

Where is the study run from?
Department of Ophthalmology, Chonnam National University Medical School and Hospital (South Korea).

When is the study starting and how long is it expected to run for?
From January 2015 to March 2015.

Who is funding the study?
Investigator initiated and funded (South Korea).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effect of topical administration of TRPM8 agonist in patients with dry eye disease: a single-center randomized double-masked vehicle-controlled study

Acronym
TRPM8 (transient receptor potential melastatin 8)

Study objectives
Topical administration of TRPM8 agonist may increase basal tear production in patients with mild to moderate dry eye disease. Also, it may provide short-term symptom relief of ocular dryness.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board of Chonnam National University Hospital, 10/07/2014, IRB No. CNUH 2014-171

Study design
Single-center randomized double-masked vehicle-controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Dry eye is a disorder of the tear film due to tear deficiency or excessive evaporation, which causes damage to the interpalpebral ocular surface and is associated with symptoms of ocular discomfort.

Interventions
TRPM8 agonist (1-(Diisopropyl-phosphinoyl)-nonane) dissolved in distilled water (2 mg/mL) or vehicle (distilled water) was topically delivered using the absorbent cotton gauze square (0.4 g rectangle (50 mm x 60 mm), CS-being, Daisan Cotton, Japan) and wiped twice across the closed eyelid. A loading volume of 0.5 mL of solution on cotton was used to wet the cotton.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
1-(Diisopropyl-phosphinoyl)-nonane

Primary outcome measure
1. Basal tear secretion (baseline and every 20 minutes) – assessed by Schirmer score
2. Dry eye symptom (baseline and after 60 minutes): using the questionnaire (0, no symptoms; 1, mild symptoms; 2, moderate symptoms; 3, severe symptoms; and 4, very severe symptoms)

Secondary outcome measures
1. Cooling sensation (baseline and every 5 minutes) – assessed by visual analogue scale (VAS) (0 to 10)
2. Tear-film break up time (baseline and every 10 minutes) - the time before the defect of fluorescein dye appeared in the stained tear film was measured and recorded (measured TBUT 3 times and averaged)
3. Corneal sensitivity (baseline and every 20 minutes) – measured using the Cochet-Bonnet esthesiometer

4. Keratoepitheliopathy score (baseline and every 30 minutes) – after staining the cornea with fluorescein dye, the score was obtained by multiplying the stained area (0-3) by stained density (0-3)
Area (0, no punctate staining; 1, area occupied less than 1/3 of the cornea; 2, area occupied 1/3 to 2/3 of the cornea; 3, area occupied greater than 2/3 of the cornea)
Density (0, no punctate staining; 1, sparse density; 2, moderate density; 3, high density and the overlapped lesions)

These outcomes were measured for 1 hour (60 minutes)

Overall study start date
01/01/2015

Completion date
01/03/2015

Eligibility

Key inclusion criteria
1. Dry eye symptoms for more than 3 months despite the use of artificial tears
2. Low tear film break-up time (TBUT) (≤ 7 seconds)
3. Low Schirmer score (≤ 10 mm/5 min)
4. Presence of corneal and conjunctival epithelial damage

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60 patients (30 patients in each group)

Key exclusion criteria
1. History of any ocular disease other than DED
2. Meibomian gland dysfunction
3. Contact lens use
4. Ocular trauma or surgeries
5. Presence of an uncontrolled systemic disease that could affect ocular surface condition
6. Punctual plugs
7. Used any eye drops other than artificial tears
8. Used any systemic medication that can cause dry eye
9. Pregnant

Date of first enrolment
09/01/2015

Date of final enrolment
16/02/2015

Locations

Countries of recruitment
Korea, South

Study participating centre
Department of Ophthalmology, Chonnam National University Medical School and Hospital
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Sponsor information

Organisation
Chonnam National University Medical School and Hospital

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Sponsor type
University/education

ROR
https://ror.org/00f200z37

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (South Korea)

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	26/06/2017	25/06/2020	Yes	No