

# Ocular effect of TRPM8 agonist in patients with dry eye disease

<b>Submission date</b> 17/03/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 21/03/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/06/2020	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data

## 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

**Contact name**

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## Additional identifiers

## 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

**Study type(s)**

Treatment

## 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(s)

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)

## Key secondary outcome(s))

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)

## 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) ( $\leq 7$  seconds)
3. Low Schirmer score ( $\leq 10$  mm/5 min)
4. Presence of corneal and conjunctival epithelial damage

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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

## ROR

<https://ror.org/00f200z37>

# Funder(s)

## Funder type

Other

## Funder Name

Investigator initiated and funded (South Korea)

# Results and Publications

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Other

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	26/06/2017	25/06/2020	Yes	No