

# Ectopic activation of TRPM8 with a newly-developed agonist relieves dry-eye symptoms

<b>Submission date</b> 01/09/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 02/09/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 23/01/2019	<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 daily topical administration of a drug called a 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?

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 to the upper eyelid 4 times daily (every 6 hours) for 2 weeks with using a stick filled with TRPM8 agonist or distilled water only.

### What are the possible benefits and risks of participating?

The treatment may relieve dry eye related eye symptoms. There are no 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 August 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

Prof Kyung Chul Yoon

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## Contact details

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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 daily topical administration of TRPM8 agonist in patients with mild to moderate dry eye disease: a single-center randomized double-masked vehicle-controlled study

## Study objectives

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. Daily topical administration of TRPM8 agonist may increase basal tear production in patients with mild to moderate dry eye disease. Also, it may provide symptom relief and improve patients quality of life related to ocular discomfort.

## 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

**Interventions**

Patients will be randomized to be treated with TRPM8 agonist (1-(Diisopropyl-phosphinoyl)-nonane) dissolved in distilled water (2 mg/mL) or vehicle (distilled water) topically delivered using the stick and topically applied in the margin of upper eyelid 4 times daily (every 6 hours) for 2 weeks.

**Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

1-(Diisopropyl-phosphinoyl)-nonane

**Primary outcome measure**

1. Basal tear secretion (baseline, 1 week, and 2 weeks follow-up) – assessed by Schirmer score
2. Symptom score assessed by three questionnaires at baseline, 1 week, and 2 weeks follow-up:
  - 2.1. Visual analogue score (VAS)
  - 2.2. Ocular surface disease index (OSDI)
  - 2.3. Computer vision syndrome (CVS) related symptoms

**Secondary outcome measures**

1. Tear-film break up time (baseline, 1 week, and 2 weeks follow-up) - the time before the defect of fluorescein dye appeared in the stained tear film was measured and recorded (measured TBUT 3 times and averaged)
2. Keratoepitheliopathy score (baseline, 1 week, and 2 weeks follow-up) – 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)

**Overall study start date**

01/01/2015

**Completion date**

31/08/2015

## 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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

At least 40 patients (20 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**

01/07/2015

**Date of final enrolment**

01/08/2015

# Locations

## Countries of recruitment

Korea, South

## Study participating centre

### Department of Ophthalmology

Chonnam National University Medical School and Hospital

Korea, South

KS0008

# Sponsor information

## Organisation

Chonnam National University Medical School and Hospital

## Sponsor details

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## Sponsor type

University/education

## ROR

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

# Funder(s)

## Funder type

Other

## Funder Name

Investigator initiated and funded

# 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

Not expected to be made available

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	26/06/2017	23/01/2019	Yes	No
<a href="#">Results article</a>	results	15/11/2018	23/01/2019	Yes	No