

# Use of artificial tears in patients treated with eye (intravitreal) injections

<b>Submission date</b> 30/01/2021	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 17/02/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/12/2022	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Current plain English summary as of 06/04/2021:

### Background and study aims

An intravitreal injection is a shot of medicine into the eye. The inside of the eye is filled with a jelly-like fluid (vitreous). During this procedure, your health care provider injects medicine into the vitreous, near the retina at the back of the eye. The medicine can treat certain eye problems and help protect your vision. This method is most often used to get a higher level of medicine to the retina.

This treatment is a likely factor in the development of dry eye syndrome.

The aim of this study is to evaluate the benefit of use of artificial tears in patients submitted to this treatment.

### Who can participate?

Patients aged 50+ years with anti-vascular endothelial growth treatment

### What does the study involve?

Participants will be randomly allocated to receive Systane Ultra Plus Hydration or Viscofresh 10mg/ml eye drops. At baseline, at 7, 30, 37 and 60 days after baseline, the eyes will undergo an examination.

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

The potential benefits of the study and for the individual study participant in the study group are that the use of artificial tears during anti-vascular endothelial growth treatment may reduce ocular discomfort.

Risks: None

### Where is the study run from?

Oftalvist (Spain)

### When is the study starting and how long is it expected to run for?

December 2020 to August 2022

Who is funding the study?  
Oftalmología Vistahermosa SL (Spain)

Who is the main contact?  
Dr Francisco Pastor-Pascual, franciscopastorpascual@gmail.com

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
ITT#63239827

## Study information

**Scientific Title**  
Ocular discomfort following use of artificial tears in patients under treatment of intravitreal injections of anti-vascular endothelial growth factor agents

**Acronym**  
Antiveg-tears

**Study objectives**  
The use of lubricant after intravitreal injections reduces the symptoms of ocular surface discomfort

**Ethics approval required**  
Old ethics approval format

## Ethics approval(s)

Approved 23/03/2021, Hospital Clinico San Carlos (Puerta G - 4ª Norte, Madrid 28040 Madrid, Spain; +34 91 330 34 13; ceic.hcsc@salud.madrid.org), ref: 21/164-EC\_P

## Study design

Two arm randomized prospective comparative examiner masked clinical study

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Age-related macular degeneration

## Interventions

Current interventions as of 06/04/2021:

All patients will be randomly assigned to use one of two treatments (Dose A: Viscofresh 10mg/ml or Dose B: Systane Ultra Plus Hydration). Before randomization, all patients will be evaluated at the first recruitment visit (without Dose). After this first visit, if they are included, they will be assigned with the treatment of Dose A or Dose B. At the end of the visit they will receive the Ranibizumab injection (following their usual treatment) and will not receive any dose. They will be subsequently evaluated a week and a month. At the end of the month's visit, they will receive a Ranibizumab injection and the Dose prescribed (A or B depending on randomization). The next visit will be at one week and one month to evaluate the results.

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Previous interventions:

All patients will be randomly assigned to use one of two treatments (Dose A: 0.9% saline or Dose B: Systane Ultra Plus Hydration). Before randomization all patients will be evaluated at the first recruitment visit (without Dose). After this first visit, if they are included, they will be assigned with the treatment of Dose A or Dose B. At the end of the visit they will receive the Ranibizumab injection (following their usual treatment) and will not receive any dose. They will be subsequently evaluated a week and a month. At the end of the month's visit, they will receive a Ranibizumab injection and the Dose prescribed (A or B depending on randomization). The next visit will be at one week and one month to evaluate the results.

## Intervention Type

Other

## Primary outcome(s)

Ocular Surface Discomfort Index questionnaire measured at baseline, 7, 30, 37 and 60 days.

## Key secondary outcome(s)

Measured at baseline, 7, 30, 37 and 60 days:

1. Meniscus tear height measured using Keratograph device
2. Conjunctival hyperemia measured using Keratograph device

3. Non-invasive keratographic tear film break-up time (BUT) measured using Keratograph device
4. Dry eye symptoms measured using the DEQ-5 questionnaire
5. Corneal staining measured using Keratograph device
6. Fluorescein BUT measured using Keratograph device
7. Meibomiography measured using Keratograph device

**Completion date**

03/08/2022

## Eligibility

**Key inclusion criteria**

Current inclusion criteria as of 06/04/2021:

1. Patients with anti-vascular endothelial growth treatment with Lucentis 10mg/ml (ranibizumab, Novartis) for age-related macular degeneration
2. Patients must have already received a minimum of three injections of this treatment
3. Age between 51 and 90 years

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Previous inclusion criteria:

1. Patients with anti-vascular endothelial growth treatment with Lucentis 10mg/ml (ranibizumab, Novartis) for age-related macular degeneration
2. Patients must have already received a minimum of three injections of this treatment
3. Age between 50 and 90 years

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Total final enrolment**

34

**Key exclusion criteria**

1. Glaucoma
2. Dry eye
3. Previous refractive surgery or recent cataract surgery (less than 6 months)

**Date of first enrolment**

01/04/2021

**Date of final enrolment**

01/09/2021

## Locations

**Countries of recruitment**

Spain

**Study participating centre****Oftalvist**

Av. de la Ilustración, 1

Burjassot

Spain

46100

## Sponsor information

**Organisation**

Oftalmología Vistahermosa SL

## Funder(s)

**Funder type**

Other

**Funder Name**

Investigator initiated and funded

## Results and Publications

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		30/11/2022	08/12/2022	Yes	No

