ISRCTN77853517 https://doi.org/10.1186/ISRCTN77853517

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

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 30/01/2021 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 17/02/2021 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 08/12/2022 | Eye Diseases | |

**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

### Contact name
Dr Francisco Pastor-Pascual

### Contact details
Oftalvist. Av. de la Ilustración, 1
Burjassot
Spain
46100
+34 963 00 30 18
fpastor@oftalvist.es

# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
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 intravitreous 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

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

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

## 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.

———

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

### Secondary outcome measures
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 devie

### Overall study start date
01/12/2020

### 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

_____

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

### Age group
Adult

**Sex**
Both

**Target number of participants**
40

**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

**Sponsor details**
Av. de la Ilustración, 1.
Burjassot
Spain
46100
+34 628379731
maria.cobo@oftalvist.es

**Sponsor type**
Hospital/treatment centre

**Website**
https://www.oftalvist.es

# Funder(s)

**Funder type**
Other

**Funder Name**
Investigator initiated and funded

# Results and Publications

**Publication and dissemination plan**
Planned publication in a high-impact peer-reviewed journal.

**Intention to publish date**
01/12/2022

**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? |
|---|---|---|---|---|---|
| Results article | | 30/11/2022 | 08/12/2022 | Yes | No |