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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
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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 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

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 devie

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
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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?
Results article		30/11/2022	08/12/2022	Yes	No

Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes