The study is made up of 3 parts.

Screening period (up to 4 weeks)

• You will visit the study centre to see if the study is suitable for you and whether you want to take part.

Study treatment period (about 48 weeks)

- You will visit the study centre up to 11 times for study assessments.
- You will receive the study medication once every 4 weeks for the first 3 doses, then once every 8 weeks until the end of the study.
- You will also have safety phone calls after each study medication dose.

Follow-up period (about 4 weeks)

• You will visit the study centre once for study assessments after you have finished taking the study medication.



What else do I need to consider?

- The study team will explain the possible benefits and risks of the study.
- You do not have to take part in the study if you do not want to.
- If you choose to take part in the study, you can stop participating at any time.
- You will not be paid to take part in this study, but you may be reimbursed for reasonable travel costs during your participation.
- All study medication and study-related tests will be provided at no cost to you.
- A team of doctors and nurses will monitor your health carefully during the study.



How do I get more information?

To find out more, contact the study team using the information provided here.

Study participation is voluntary. By contacting us, you are under no obligation to take part in the study.

Pretoria Eye Institute Clinical Research Department

- T: 012 427 0000/2204/2315
- E: research@eyeinstitute.co.za



We understand what is at the centre of your world.

We're

aiming to

create a

brighter

future

for all





Join a clinical research study and help us improve patient access to wet age-related macular degeneration treatments

What is a clinical research study?

A clinical research study is a medical study that helps to answer important questions about an investigational medication, such as:

- Does it work?
- What amount, or dose, may work best?
- How safe is it?
- Are there side effects?

All medications must be tested in clinical research studies before they can be approved to prescribe to patients. Without people taking part in these studies, we would have no new medications.



Deciding to take part in a clinical research study is an important decision. If you have any questions, please contact the study team using the information provided in this brochure.

About the ALVOEYE Study

The ALVOEYE Study is a clinical study researching an investigational medication for people with wet age-related macular degeneration (wet AMD, also called neovascular AMD).

This study is looking at whether the investigational medication is safe and works in a similar way to Eylea[®] (the brand name for aflibercept). Aflibercept is a medication for wet AMD that is already approved for use.

The investigational medication is a proposed 'biosimilar' to Eylea[®]. A biosimilar medication is a new version of an already existing biologic medication.





Why is the ALVOEYE Study important?

Wet AMD is a condition that causes abnormal blood vessels in the eye to grow, bleed and leak fluid, leading to a rapid loss of vision. There are many treatments available for people with wet AMD, however, they can be expensive. Therefore, it is important to research new, more affordable treatment options.

The investigational medication is an intravitreal (inside the eye) injection. It is designed to work in the same way as Eylea[®], by blocking a protein involved in the growth of blood vessels in the eye. By blocking this protein, abnormal blood vessels cannot develop, so the symptoms of wet AMD are lessened.

What will the ALVOEYE Study involve?

If you take part, you will be in the study for up to 56 weeks (about 1 year). You will:

- visit the study centre up to 13 times
- be randomly assigned to the investigational medication or Eylea® (known together as 'study medication').

You will have an equal chance of receiving either study medication. Neither you nor the study doctor will know which study medication you are receiving.



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Who can take part?

You may be able to take part if you:

- are 50 years of age or older
- have been diagnosed with wet AMD
- have not previously received any treatment for wet AMD.