

# Floater Intervention Study (FLIES): supplementation trial for the reduction of visual disturbances associated with vitreous floaters

<b>Submission date</b> 25/10/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 31/10/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 07/02/2018	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Floaters are moving shapes that people see floating in their vision. They can look like dots, shadows, clouds or strands. Floaters are usually harmless and don't impact vision. However, when they move into our line of vision, they can interfere with many everyday tasks such as reading or driving. As floaters results from changes to the vitreous (a clear, jelly-like fluid in the eye), an intervention with food supplementation comprising of water-soluble antioxidants (molecules that stop oxidation), modulators of the glycation of collagens, and inhibitors of connective tissue degrading enzymes are an option to treat them. The food supplement "VitroCap NEM" could be used to help treat floaters. The aim of this study is to investigate if the food supplement VitroCap NEM can reduce visual disturbances in the vitreous.

### Who can participate?

Patients aged 18 and older who have floaters in their eyes.

### What does the study involve?

Participants are randomly allocated to one of two groups. One of these groups will receive the placebo capsule to taken daily by mouth for six months. The other group will receive the VitroCap NEM capsules (containing specially prepared from grape seeds and citrus fruits as well as vitamins) to take daily by mouth for six months. Participants are followed up at six months to assess the change in vitreous floater disturbances.

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

Participants may benefit from the treatment. There are no direct risks to volunteers participating in this research. We will inform the participant's doctor that they will be participating in our research study.

### Where is the study run from?

NOW-Science Consultancy Limited (Ireland)

When is the study starting and how long is it expected to run for?  
January 2017 to December 2018

Who is funding the study?  
ebiga-VISION GmbH (Germany)

Who is the main contact?  
Professor John Nolan

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof John Nolan

**Contact details**  
Carriganore House  
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## Additional identifiers

**Protocol serial number**  
FLIES Version 1

## Study information

**Scientific Title**  
Floater Intervention Study (FLIES)

**Acronym**  
FLIES

**Study objectives**  
The aim of the study is to investigate if supplementation with VitroCap NEM reduces visual disturbances associated with the degeneration of the vitreous body of the eye (i.e. eye floaters disturbances).

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
Research Ethics Committee, HSE, South East, Ireland, 24/04/2017

## **Study design**

Single-centre double-blind placebo-controlled randomised interventional trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

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

Vitreous floaters

## **Interventions**

60 participants are randomised in a 50:50 masked fashion to either active ingredient (VitreCap NEM) or placebo. Block randomisation is performed using a trial management system "Trial Controller" designed by our research group.

Active group: Participants are given VitroCap NEM capsules (containing specially prepared plant ingredients from grape seeds and citrus fruits as well as vitamin C, the amino acid L-lysine, and zinc) to take daily for a total period of 6 months.

VitreCap NEM exact contents are as follows:

1. 125 mg of L-lysine
2. 40 mg of vitamin C
3. 25 mg of Vitis vinifera extract (procyanidines)
4. 5 mg of zinc
5. 60 mg of Citrus aurantium flavonoids

Placebo group: Participants are given placebo capsules to take daily for a total period of 6 months.

Participants in both groups are asked to attend study visits at baseline and 6-months.

## **Intervention Type**

Supplement

## **Primary outcome(s)**

Change in floater disturbance is measured using a subjective questionnaire following 6 months of intervention. This will be achieved by comparing the difference in change of floater-related disturbance in participants on the active intervention versus participants on the placebo intervention.

## **Key secondary outcome(s)**

1. Visual function is measured using the Early Treatment Diabetic Retinopathy Study (ETDRS) logarithm of the minimum angle of resolution (LogMAR) chart (Test Chart 2000 PRO™) for Best-corrected visual acuity (BCVA); the LogMAR EDTRS (Test Chart 2000 PRO™) for Letter Contrast Sensitivity (CS); the "Advanced Vision and Optometric Tests" (AVOT) for visual acuity, contrast sensitivity, cone and rod vision; MultiQuity (MiQ) test Suite for visual acuity and contrast sensitivity at baseline and 6-months
2. Macular pigment is measured using dual-wavelength autofluorescence, a video of floaters are captured using Scanning Laser Ophthalmoscopy (SLO) and retinal layers are measured using Optical Coherence Tomography (OCT). All outcomes listed use the Spectralis HRA + OCT

Multicolour, Heidelberg at baseline and 6-months

3. Colour fundus photographs are captured using a Zeiss Visucam at baseline and 6-months

4. Reaction time is measured using the Cognition tests the Cambridge Neuropsychological Test Automated Battery (CANTAB) at baseline and 6-months

5. Blood samples are taken to measure sodium, potassium, chloride, urea, creatinine, bilirubin, alanine aminotransferase, alkaline phosphatase, aspartate aminotransferase, gamma-glutamyl transferase, total protein, albumin, globulin, calcium, magnesium, phosphate, uric acid, vitamin C, glucose, highly sensitive C-reactive protein, and full blood count concentrations at baseline and 6-months

**Completion date**

31/12/2018

**Eligibility**

**Key inclusion criteria**

1. Patients who report primary floaters to their ophthalmologist
2. 18 years and older

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. No secondary floaters (e.g. haemorrhage)
2. Any doctor diagnosis of retinal pathology (e.g. glaucoma, age-related macular degeneration, macular oedema, retinal detachment or scars)
3. Laser eye surgery or vitrectomy performed or scheduled in the duration of the study
4. Pregnancy
5. Alcohol or drug abuse
6. Legal incompetence or restricted legal capacity
7. Cataract surgery scheduled within the duration of this trial
8. Refractive error greater than -3D
9. Axial length longer than 25mm

**Date of first enrolment**

24/10/2017

**Date of final enrolment**

28/02/2018

## Locations

### Countries of recruitment

Ireland

### Study participating centre

NOW-Science Consultancy Limited

Waterford

Ireland

X91 K236

## Sponsor information

### Organisation

NOW-Science Consultancy Limited

## Funder(s)

### Funder type

Industry

### Funder Name

ebiga-VISION GmbH

## Results and Publications

### Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

### IPD sharing plan summary

Data sharing statement to be made available at a later date