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

Submission date 25/10/2017	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 31/10/2017	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 07/02/2018	**Condition category** Eye Diseases	[_] Individual participant data [_] 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
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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 (VitroCap 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.
VitroCap 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 aurantinium 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 autoflourescence, 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes