# Assessing the effects of supplementation with Nutrof® Total on the ability of the eye to filter blue light

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
11/11/2013	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
21/11/2013	Completed	Results
Last Edited	Condition category	Individual participant data
23/01/2017	Eye Diseases	[] Record updated in last year

# Plain English summary of protocol

Background and study aims

Nutrof® Total contains nutrients considered essential for effective protection of the eye from harmful blue light (light from electronic devices such as laptop, mobile, etc). Taking the supplement for an extended time should result in a more effective filter of this blue light i.e. the supplements should increase the macular pigment levels which will protect the retina from the harmful blue light.

#### Who can participate?

Healthy volunteers aged 50+, who do not have diabetes, are not pregnant or planning to become pregnant, are not taking oral contraceptives, do not have a history of estrogen sensitive cancers, are not taking warfarin, do not have neovascular age-related macular degeneration (an eye disease), and have no other ocular pathologies that may interfere.

## What does the study involve?

All participants will have to take one food supplement capsule (Nutrof® Total) daily, for 6 months.

After 6 months the changes in blue light filtration will be measured. Blue light filtration is measured using a simple test where the time taken for a user to notice a flickering light is measured and will be carried out at 0 days, 21 days, 3 months and 6 months.

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

Nutrof® Total is a nutritional supplement that aims to ensure you have adequate levels of key nutrients essential for healthy eyes. As the ingredients can all be found to some extent in healthy diets, the only risks are from having excessive amounts of these nutrients, which may happen if the participant currently takes additional supplements. This risk will be assessed upon initial contact.

#### Where is the study run from?

The study is being run in the Macclesfield/Manchester area (UK) with the help of two local optometrists.

When is the study starting and how long is it expected to run for? The study started in September 2013 and will run until August 2014.

Who is funding the study? Technology Strategy Board (UK) and Aston University (UK).

Who is the main contact? Adam McGuinness mcguinna@aston.ac.uk

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Frank Eperjesi

#### Contact details

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# Additional identifiers

#### Protocol serial number

N/A

# Study information

#### Scientific Title

Assessing the effects of supplementation with Nutrof® Total on macular pigment optical density

# **Study objectives**

Supplementation over 6 months with Nutrof® Total should increase macular pigment levels, when measured with Tinsley MPOD®.

# Ethics approval required

Old ethics approval format

# Ethics approval(s)

Aston University Ethics Committee, 02/09/2013, REC Reference: Ethics Application 531

# Study design

Open label multi-centre intervention study

## Primary study design

Interventional

# Study type(s)

Treatment

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

Macular pigment, eye health, age related macular degeneration.

#### **Interventions**

Subjects will be required to take one food supplement capsule (Nutrof® Total) daily, for 6 months. There is no placebo. Deviation from baseline measurement will be assessed.

#### Intervention Type

Drug

#### Phase

Not Applicable

# Drug/device/biological/vaccine name(s)

Nutrof® Total

## Primary outcome(s)

Macular pigment optical density (MPOD) will be measured in the patients eye using a Tinsley® MPOD. These readings will be taken at baseline, 21 days, 3 months and 6 months.

# Key secondary outcome(s))

No secondary outcome measures

# Completion date

01/08/2014

# **Eligibility**

# Key inclusion criteria

- 1. Healthy volunteers recruited from local optometrists
- 2. Male or female
- 3. Aged 50 or older

# Participant type(s)

Healthy volunteer

# Healthy volunteers allowed

No

# Age group

Adult

#### Sex

All

# Key exclusion criteria

- 1. Type 1 and 2 diabetics
- 2. Pregnancy or intention to become pregnant
- 3. History of estrogen sensitive cancer
- 4. Warfarin users
- 5. Neovascular age-related macular degeneration (AMD) sufferers

#### Date of first enrolment

02/09/2013

#### Date of final enrolment

01/08/2014

# Locations

#### Countries of recruitment

United Kingdom

England

# Study participating centre

**Aston University** 

Birmingham United Kingdom B4 7ET

# Sponsor information

#### Organisation

Spectrum Thea Pharmaceuticals (UK)

#### **ROR**

https://ror.org/04edz9p52

# Funder(s)

#### Funder type

Research organisation

#### **Funder Name**

Technology Strategy Board (UK)

# Alternative Name(s)

TSB

#### **Funding Body Type**

Private sector organisation

## **Funding Body Subtype**

For-profit companies (industry)

#### Location

United Kingdom

#### **Funder Name**

Aston University (UK) - Spectrum Thea Pharmaceuticals (UK) - Knowledge Transfer Partnership (KTP)

# **Results and Publications**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

## **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