

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

Submission date 11/11/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/11/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 23/01/2017	Condition category 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

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?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Non randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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.

Secondary outcome measures

No secondary outcome measures

Overall study start date

02/09/2013

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

Age group

Adult

Sex

Both

Target number of participants

32

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

England

United Kingdom

Study participating centre

Aston University

Birmingham

United Kingdom

B4 7ET

Sponsor information

Organisation

Spectrum Thea Pharmaceuticals (UK)

Sponsor details

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Sponsor type

Industry

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration