ISRCTN79841039 https://doi.org/10.1186/ISRCTN79841039

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

Registration date
21/11/2013

Overall study status
Completed

Last Edited
23/01/2017

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

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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)

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Fernbank House
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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