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The effect of lutein supplementation on macular pigment density in patients who have undergone cataract surgery

Submission date 04/11/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 25/11/2009	**Overall study status** Completed	
Last Edited 25/11/2009	**Condition category** Eye Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Catherine Creuzot-Garcher

Contact details
Hopital Général Service d'ophtalmologie
3 rue de Faubourg Raines
Dijon Cedex
France
BP151921034

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
#462

Study information

Scientific Title
Prospective, open, pilot study of oral supplementation with lutein in patients having undergone cataract surgery: effect on macular pigment density

Acronym
Lutein Pilot Study

Study objectives
In this study will be tested the hypothesis that a 6 month treatment, after cataract surgery, of lutein at a dosage of 10 mg daily, significantly increases macular pigment optical density as measured by a Raman spectrometer. The null hypothesis, expected to be rejected, is that there is no difference between the measurement just after surgery and the measurement 6 months after surgery. An additional hypothesis, that a 2 month treatment of lutein increases macular pigment optical density before cataract surgery, will also be tested.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local medical ethics committee (Comite consultatif de protection des personnes dans la recherche biomedicale de Bourgogne) approved on the 9th May 2006

Study design
Prospective open monocentric non-controlled pilot study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

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
Cataract

Interventions
This was an open-label pilot study at a single site to assess if eight months of lutein supplementation results in a significant increase in macular pigment optical density and plasma lutein levels to protect the macula of subjects after cataract surgery.

There was no control group in this study.

A total of at least 40 subjects were planned for enrolment in this single site study. All included subjects received 10 mg soft capsules of lutein (containing lutein and vitamin E). Each subject was to swallow one capsule daily with a glass of water without chewing. The planned treatment duration was eight months.

Cataract surgery was to be scheduled two months after enrolment. One week after surgery, data was to be collected to establish baseline information for post-surgery MPOD.

A follow-up visit was planned for two months (+/- 7 days) following surgery and the final follow-up visit was planned for six months (+/- 2 weeks) after surgery.

Intervention Type
Drug

Phase
Phase IV

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

Primary outcome measure
To check that lutein supplementation of 10 mg results in significant Macular pigment optical density (MPOD) increase to protect the macula of patients after cataract surgery and significant increase in lutein plasma levels

Secondary outcome measures
1. Macular pigment optical density increase after lutein supplementation before surgery to protect the macula during surgery
2. Plasma levels of lutein to check treatment compliance
3. Safety of oral lutein supplementation

Overall study start date
05/07/2006

Completion date
24/10/2008

Eligibility

Key inclusion criteria
1. Men or women aged over 55 years
2. Having to undergo cataract surgery on one eye (study eye) with extracapsular cataract extraction (ECCE) by phacoemulsification and insertion of a posterior chamber implant
3. Written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
At least 40

Key exclusion criteria
1. Body mass index (BMI) greater than or equal to 29 kg/m^2
2. Poor pupillary dilation less than 6 mm with mydriatic drugs
3. Age-related maculopathy or macular degeneration (Age-Related Eye Disease Study [AREDS] class 2, 3 or 4)
4. Diabetic retinopathy
5. History of other progressive disease in the study eye which may complicate the assessment of pigment density
6. Known sensitivity to lutein, vitamin E or vehicules
7. Use of cholesterol-lowering drugs that act as bile acid binders (may interfere with carotenoid absorption) within the last month
8. Concomitant disease or therapy which could interfere with lutein absorption
9. Supplementation with carotenoids within the previous 6 months
10. Drastic change of food and/or food supplements within the last month
11. Involvement in the last 30 days in any investigational drug study

Date of first enrolment
05/07/2006

Date of final enrolment
24/10/2008

Locations

Countries of recruitment
France

Study participating centre
Hopital Général Service d'ophtalmologie
Dijon Cedex
France
BP151921034

Sponsor information

Organisation

Dr. Mann Pharma GmbH, Bausch & Lomb Group (Germany)

Sponsor details
Brunsbütteler Damm 165 - 173
Berlin
Germany
13581

Sponsor type
Industry

Website
http://www.bausch-lomb.de/

ROR
https://ror.org/049ncrn81

Funder(s)

Funder type
Industry

Funder Name
Dr. Mann Pharma GmbH, Bausch & Lomb Group (Germany)

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