

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 25/11/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 25/11/2009	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

#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 biomédicale de Bourgogne) approved on the 9th May 2006

Study design

Prospective open monocentric non-controlled pilot study

Primary study design

Interventional

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Body mass index (BMI) greater than or equal to 29 kg/m²
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 vehicles
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)

ROR

<https://ror.org/049ncrn81>

Funder(s)

Funder type

Industry

Funder Name

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration