

Lutein and zeaxanthin supplementation in preterm infants to prevent retinopathy of prematurity

Submission date 12/05/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/06/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 23/05/2017	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Retinopathy of prematurity is a disease that occurs in premature babies where abnormal blood vessels grow in the retina (the layer of nerve tissue in the eye). This growth can cause the retina to detach from the back of the eye, causing blindness. The aim of this study is to find out whether lutein and zeaxanthin supplements can prevent retinopathy of prematurity in preterm infants.

Who can participate?

Preterm infants (gestational age 32 weeks or less)

What does the study involve?

Participants are randomly allocated to receive a daily dose of lutein and zeaxanthin or a placebo (dummy drug) until discharged from hospital. The occurrence of retinopathy of prematurity is recorded in both groups to see whether the supplement prevents retinopathy of prematurity.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

Careggi University Hospital of Florence (Italy)

When is the study starting and how long is it expected to run for?

February 2008 to February 2011

Who is funding the study?

SOOFT Italia S.p.a. (Italy)

Who is the main contact?

Prof. Carlo Dani

Contact information

Type(s)

Scientific

Contact name

Prof Carlo Dani

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

01/2008

Study information

Scientific Title

LUtein and zeaxanthin SUPplementation in Preterm infants to prevent RetinOpathy of Prematurity: a multicentre prospective randomised double-blind placebo-controlled study

Acronym

LUSUPROP Study

Study objectives

Retinopathy of prematurity (ROP) that was classified according to the International Classification as follows:

Stage 1, a thin demarcation line separates the avascular retina anteriorly from the vascularized retina posteriorly

Stage 2, a ridge arises in the region of the demarcation line and extends above the plane of the retina

Stage 3, neovascularization extends from the ridge into the vitreous

Stage 4, there is partial retinal detachment; stage 5, there is total retinal detachment

Moreover, increased venous dilation and arteriolar tortuosity are markers of severe active ROP and are referred to as plus disease.

Lutein and zeaxanthin supplementation may decrease the occurrence of retinopathy of prematurity (ROP) in high risk preterm infants.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee for Clinical Trials of Medicines, University Hospital Careggi (Comitato Eitco per la sperimentazione clinica dei medicinali, Azienda ospedaliera Universitaria Careggi), 25/05/2007, ref: 38/2009

Study design

Multicentre prospective randomised double-blind placebo-controlled study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

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

Health condition(s) or problem(s) studied

Retinopathy of prematurity (ROP)

Interventions

Infants at each unit were grouped in blocks:

1. 1st block: gestational age < 25+6 weeks
2. 2nd block: gestational age from 26+0 to 28+6 weeks
3. 3rd block: gestational age > 29+0 weeks)

Infants were randomly assigned to a treatment group using the sealed envelope technique which were prepared at Careggi University Hospital of Florence and then distributed to participating centres. Each infant received a daily oral dose of 0.5 ml containing 0.14 mg of lutein and 0.006 mg of zeaxanthin (LUTEINofta®, Sooft Italia, Montegiorgio, Italy) or indistinguishable placebo. Supplementation was begun from the 1st to the 7th day of life and was given until discharge. Lutein/Zeaxanthin (L/Z) or placebo were given before feeding or added to breast milk (from the infant's mother or a donor) or to infant formula. Age and duration of supplementation were recorded. Time of initial feeding, use of breast milk or preterm infant formula, and change from preterm infant formula to term infant formula were at the discretion of the attending physician.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. The successful rate of lutein and zeaxanthin supplementation at preventing ROP
2. The rate of primary endpoint was calculated on the basis of collected data and in agreement with those from literature, while the duration of follow up was decided on the basis of recommendation of the Italian Society of Neonatology and in agreement with the current literature

Secondary outcome measures

1. Gestational and post-natal age at ROP diagnosis
2. The need for surgical treatment (laser- or cryo-therapy)
3. The incidence of sepsis, intraventricular hemorrhage (IVH), periventricular leukomalacia (PVL), bronchopulmonary dysplasia (BPD), necrotizing enterocolitis (NEC) and mortality

Overall study start date

01/02/2008

Completion date

28/02/2011

Eligibility**Key inclusion criteria**

Infants with gestational age < 32 weeks after parental informed consent

Participant type(s)

Patient

Age group

Neonate

Sex

Both

Target number of participants

242

Key exclusion criteria

1. The presence of major congenital malformation
2. Fetal hydrops
3. Death before the first ophthalmologic examination
3. Lack of lutein supplementation > 10 days during the first 30 days of life
4. Development of aggressive-posterior ROP (AP-ROP)

Date of first enrolment

01/02/2008

Date of final enrolment

28/02/2011

Locations

Countries of recruitment

Italy

Study participating centre

Careggi University Hospital of Florence

Florence

Italy

50141

Sponsor information

Organisation

University of Florence (Italy)

Sponsor details

Department of Surgical and Medical Critical Care

Viale Morgagni 85

Florence

Italy

50141

Sponsor type

University/education

ROR

<https://ror.org/04jr1s763>

Funder(s)

Funder type

Industry

Funder Name

SOOFT Italia S.p.a. (Italy)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2012		Yes	No