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

Submission date	Recruitment status	[_] Prospectively registered
12/05/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/06/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/05/2017	Eye Diseases	

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

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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
Forence
Italy
50141

Sponsor information

Organisation
University of Florence (Italy)

Sponsor details
Department of Surgical and Medical Critical Care
Viale Morgagni 85
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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