

Lutein supplementation in very low birth weight (VLBW) neonates in neonatal intensive care units (NICU)

Submission date 15/11/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/11/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 12/04/2021	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Paolo Manzoni

Contact details

Neonatology and Hospital NICU

C. Spezia 60

Torino

Italy

10126

-

paolomanzoni@hotmail.com

Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Lutein supplementation in VLBW neonates in NICU: a double-blind, multicentre, placebo-controlled, randomised trial

Study objectives

To evaluate the efficacy of Lutein and Zeaxanthin supplementation in the prevention of Retinopathy of Prematurity (ROP), Bronchopulmonary dysplasia (BPD), Necrotising Enterocolitis (NEC) in preterm very low birth weight (i.e., <1500g at birth) infants in NICU.

Human milk feedings of preterm infants have been associated with a lower incidence of retinopathy of prematurity (ROP), a disorder affecting the retinal vessels that may lead to blindness. The carotenoids in human milk (lutein, b-carotene, zeaxanthin, lycopene) may provide the highest protection against both light-induced and metabolic oxidative damage in the retina and in other developing tissues. Carotenoids are a family of polyene, lipophilic molecules found in human milk but not in formulas and are preferentially accumulated in the eyes. Carotenoids such as Lutein and Zeaxanthin, due to their anti-oxidative properties, might be also active in prevention of a number of multifactorial diseases related to prematurity, in which an oxidative insult is crucial for the diseases onset. The aim of this study is thus to evaluate the relation of carotenoids with the development of ROP, BPD, NEC in human milk fed preterm infants.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the Ethical Committee of the Saint Anna Foundation (Fondazione Crescere insieme al Sant'Anna [ONLUS]), on behalf of each participating institution.

Study design

Multicentre prospective randomised double blind placebo controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Disorders of preterm very low birth weight infants

Interventions

1. The regimens in the two intervention groups will be :

Group A: Lutein/Zeaxanthin supplementation (14 drops, i.e. 0.5 ml, meaning 0.14 mg of Lutein and 0.0006 mg of Zeaxanthin; LuteinOfta® gtt, NEOOX Division of SOOFT Italia s.p.a., Montegiorgio, Italy; Group A)

Group B: placebo (0.5 ml of a 5% glucose solution) .

2. Drug and placebo will be administered in a single oral daily dose from birth till the 36th week of gestational age (corrected age).

3. Administration will start within the first 48 h of life

4. Neonates not feeding in the first 48 hours will receive the drug/placebo by oral/naso-gastric tube and can be enrolled in the absence of gastric instability and/or repeated gastric residuals or vomit.

5. If they repeatedly display gastric instability, gastric residuals or vomit, they may be enrolled at any point during the first week of life, depending on the first "efficacious" feedings. The day of life in which they first received the drugs/placebo is started will be recorded in the database, and their statistics will be limited to the days of administration exposure to intervention.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Lutein/Zeaxanthin (LuteinOfta®)

Primary outcome(s)

The primary objective of the study will be to evaluate the effectiveness of Lutein with Zeaxanthin compared to placebo in the prevention of ROP of any stage, BPD, and NEC of surgical stage (i.e., 2nd or greater according to Bell classification) in the preterm neonates <32+6 wks g.a. admitted to the participant NICUs. Surveillance for detection of these diseases, as well as for intolerance/adverse effects will be performed till discharge. Measurements of serum liver enzymes values will be also performed at 4 wks of age.

Key secondary outcome(s)

1. Assessment of the incidence of NEC of all stages
2. Intestinal perforation
3. Late-onset sepsis
4. Mortality prior to discharge
5. Death or NEC (all stages)
6. Death or sepsis or NEC (surgical stage)
7. Severe (grade 3-4) intraventricular haemorrhage
8. Liver failure

Completion date

31/01/2010

Eligibility**Key inclusion criteria**

All neonates with gestational age (g.a.) less than 32 wks + 6 days (i.e., all those qualifying for screening of ROP) born within the study period, whether at one of the participant Institutions or elsewhere, were eligible for the study.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

Total final enrolment

229

Key exclusion criteria

1. Parental refusal
2. Admission after 48 hours of life
3. Death prior to 72 hours of life
4. Ophtalmological disease already present at the time of randomisation

Date of first enrolment

01/07/2008

Date of final enrolment

31/01/2010

Locations**Countries of recruitment**

Italy

Study participating centre

Neonatology and Hospital NICU

Torino

Italy

10126

Sponsor information**Organisation**

Saint Anna Foundation (Fondazione Crescere Insieme al Santa Anna [ONLUS]) (Italy)

ROR

<https://ror.org/00k065b17>

Funder(s)**Funder type**

Industry

Funder Name

Sooft Italia S.p.A. (Italy) (providing Lutein+ Zeaxanthyn and placebo, and financial support)

Results and Publications

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		01/01/2013	12/04/2021	Yes	No
Abstract results		01/10/2009		No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes