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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

Registration date
23/11/2009

Overall study status
Completed

Last Edited
12/04/2021

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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), Bronchopulomonary 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 Zeaxanthyn, due to their anti-oxydative 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 SantAnna [ONLUS]), on behalf of each participating institution.

Study design
Multicentre prospective randomised double blind placebo controlled trial

Primary study design
Interventional

Secondary study design
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
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 measure
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.

Secondary outcome measures
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

Overall study start date
01/07/2008

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

Age group
Neonate

Sex
Both

Target number of participants
204

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
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Sponsor information

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

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Sponsor type
Charity

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

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?
Abstract results		01/10/2009		No	No
Results article		01/01/2013	12/04/2021	Yes	No