ISRCTN75393382 https://doi.org/10.1186/ISRCTN75393382

Effectiveness and tolerability of Sucrosomial® Iron supplementation in preterm or critically ill infants admitted to Special Neonatal Care Unit

Submission date
14/12/2023

Recruitment status
No longer recruiting

Registration date
20/05/2024

Overall study status
Completed

Last Edited
09/01/2025

Condition category
Haematological Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Iron deficiency anemia, a condition in which blood lacks adequate healthy red blood cells, affects many infants during the first months of life. Preterm birth is a condition that predisposes to its development. Furthermore, in the newborn, anemia can occur also due to several reasons such as increased destruction or decreased production of red blood cells, repeated blood tests during hospitalization and reduced iron stores. For these reasons, iron supplementation is routinely recommended by scientific guidelines, and prescribed starting from 2 weeks of life and continued after discharge. Data on tolerability show that compliance with the therapy is often suboptimal. The study aims to evaluate the effectiveness and tolerability of sucrosomial iron supplementation for 2 months after discharge, tested with monthly clinical and haematologic controls.

Who can participate?
Newborns born at less than 37 weeks of gestational age or who are ill, aged over 30 days and less than 6 months, excluding chronic diseases and/or use of drugs, with severe (Hb <9 g/dL) or mild (Hb ≥9 g/dL) anemia at discharge.

What does the study involve?
Newborns will receive iron supplementation according to clinical practice and will be evaluated by assessing clinical routine parameters for this clinical condition.

What are the possible benefits and risks of participating?
No risk to patients is expected from participation in this study. Sucrosomial iron is a food supplement with a good safety and tolerability profile. The benefits are those expected in normal clinical practice.

Where is the study run from?
Azienda Ospedaliero-Universitaria Città della Salute e della Scienza di Torino (Italy)

When is the study starting and how long is it expected to run for?
March 2023 to June 2024

Who is funding the study?
Pharmanutra SpA (Italy)

Who is the main contact?
Dr Francesco Savino, francesco.savino@unito.it

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Francesco Savino

Contact details
P.zza Polonia, 94
Turin
Italy
10126
+39 (0)116331633
francesco.savino@unito.it

Additional identifiers

Study information

Scientific Title
Sucrosomial iron supplementation in preterm or ill infants

Study objectives
Iron deficiency anemia (IDA) is the most frequent form in all ages. Preterm birth is a condition that predisposes to the development of IDA. Furthermore, in the ill newborn, anemia can occur also due to several reasons such as hemorrhages, increased destruction or decreased production of erythrocytes, repeated blood tests during hospitalization and reduced iron stores. For these reasons, iron supplementation is routinely recommended by scientific guidelines, and prescribed starting from 2 weeks of life and continued after discharge. Data on tolerability show that compliance with the therapy is often suboptimal. The objective of the study is to evaluate the effectiveness and tolerability of iron supplementation for 2 months after discharge, tested with monthly clinical and haematologic controls.

Ethics approval required
Ethics approval not required

Ethics approval(s)
Ethics committee approval is not required for observational studies based on routine care.

Primary study design

Observational

Study design
Prospective observational case series

Study type(s)
Prevention, Treatment, Safety, Efficacy

Health condition(s) or problem(s) studied
Iron deficiency or iron deficiency anemia in preterm or pathological newborns and infants

Interventions
Infants with severe (Hb <9 g/dL) or mild (Hb ≥9 g/dL) anemia at discharge are treated with respectively 3.6 and 2.4 mg/kg/day of sucrosomial iron.

Sucrosomial iron (commercial name Sideral drops Forte) is a food supplement in drops, assuming by oral route. Each drop contains 1.2 mg of elemental iron. The number of drops will be calculated according to the recommended daily dose and will be administered once a day early in the morning.

A parental diary is used to collect data about compliance and tolerability. At 1 and 2 months after discharge clinical assessment is performed, together with Hb, Hct, reticulocyte, iron, ferritin and transferrin.

Intervention Type
Supplement

Primary outcome(s)
Effectiveness assessed by measuring haemoglobin (g/dl), haematocrit (%), reticulocytes (%), mean corpuscular volume (MCV) (µm3), serum iron (µg/dl), serum ferritin (ng/ml), transferrin (g /L), and CHr (pg) using standard laboratory tests at baseline (T0), after 1 month (T1) and 2 months (T2)

Key secondary outcome(s)
1. Adherence to supplement consumption assessed using medical records for inpatients, and asking parents for outpatients, after 1 month (T1) and 2 months (T2)
2. Incidence of adverse events assessed by the PI and any qualified designees delegated by the PI documenting and recording events that meet the definition of an adverse event or serious adverse event considered related to study treatment or study procedures, or that caused the patient to discontinue the study product. Collected for the 2 months of the study.
3. Growth parameters (weight, length, head circumference) measured during physical examination at baseline (T0), after 1 month (T1) and 2 months (T2)

Completion date
01/06/2024

Eligibility

Key inclusion criteria

1. Preterm infants (gestational age at birth <37 weeks) or pathological infants admitted to the Special Neonatal care unit
2. Diagnosis of anemia according to hemoglobin levels: severe anemia with Hb <9 g/dL at baseline, and mild anemia with Hb ≥9 g/dL at baseline, independently from other hematological parameters

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Lower age limit
0 Months

Upper age limit
6 Months

Sex
All

Key exclusion criteria
1. Acute bleeding
2. Haemolytic disease
3. Short bowel syndrome
4. Severe heart congenital malformations requiring surgery

Date of first enrolment
01/06/2023

Date of final enrolment
31/03/2024

Locations

Countries of recruitment
Italy

Study participating centre
Patologia Neonatale e della Prima Infanzia del Dipartimento di Patologia e Cura del bambino "Regina Margherita" del Presidio Ospedale Infantile Regina Margherita – A.O.U. Città della Salute e della Scienza di Torino
P.zza Polonia, 94

Turin
Italy
10126

Sponsor information

Organisation
Pharmanutra Spa

Funder(s)

Funder type
Industry

Funder Name
PharmaNutra

Alternative Name(s)
Pharmanutra S.p.A., PharmaNutra SpA

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Italy

Results and Publications

Individual participant data (IPD) sharing plan
A unique subject identification code will be used that allows the identification of all data reported for each subject. Data relating to the study might be made available to third parties (for example in case of an audit performed by Regulatory Authorities, or in case of request by journal reviewers) provided the data are treated confidentially and that the subject's privacy is guaranteed. Data will be obtained and conserved according to current local regulations in order to ensure that all the requirements in terms of data protection are satisfied. The documentation that identifies the subjects enrolled in the clinical investigation will be kept reserved and will not be publicly available, according to local current regulations.

IPD sharing plan summary

Other