Effectiveness and safety of ior EPOCIM in anemia in premature infant.

---------- Public Title:
Effectiveness and safety of ior EPOCIM in anemia in premature infant.
---------- Scientific Title:
Effectiveness and Safety of use ior EPOCIM in the prophylaxis or treatment of anemia in the premature infant.Phase III
---------- Secondary Identifying Numbers:
IIC-RD-EC121
---------- Issuing Authority of the Secondary Identifying Numbers:
Center of Molecular Immunology(CIM)
---------- Primary Sponsor:
Center of Molecular Immunology(CIM)
---------- Secondary Sponsor(s):
No proceed
---------- Source(s) of Monetary or Material Support:
Goverment found
---------- Regulatory authority to approve the initiation to the study:
Center for State Control of the Quality of Medicines (CECMED)
---------- Authorization Date:
24/08/2009 00:00
---------- Reference Number:
994/05.018.09.B
---------- Countries of Recruitment:
Cuba
---------- Province of Principal Site:
Havana City
---------- Principal Clinical Site:
Mother and Child Teaching Hospital 10 de Octubre
---------- Principal Investigator:
Anett Sijó Yero,MD.First degree specialist in Neonatology.
---------- Other Clinical Sites:
Havana City, Ginecobstetric Hospital “Ramón González Coro”, Fernando Domínguez Dieppa, MD.Second degree specialist in Neonatology.
Havana City, Ginecobstetric Hospital “Eusebio Hernández”, Leonel Méndez, MD.First degree specialist in Neonatology.
Havana City, Enrique Cabrera Hospital, Debora Villegas Cruz, MD. First degree specialist in Neonatology.
Havana City, Ginecobstetric Hospital “América Arias”, Eugenio Carro Puig, MD. Second degree specialist in Neonatology.
---------- Research Ethics Committees:
Havana City, 10 de Octubre Mother and Child Teaching Hospital, May 15,2009.
Havana City, Ginecobstetric Hospital “Ramón González Coro”, May 6,2009.
Havana City, Ginecobstetric Hospital “Eusebio Hernández”, May 26,2009.
Havana City, Enrique Cabrera Hospital, May 31,2009.
Havana City, Ginecobstetric Hospital “América Arias”, May 14,2009.
---------- Recruitment Status:
1. Pending
---------- Date of First Enrollment:
---------- Health Condition(s) or Problem(s) Studied.:

Anemia in the premature infant.
---------- Intervention(s):
Schema: ior® EPOCIM+ Vitamin therapy + Ferric supplement
ior® EPOCIM 900 IU/kg/per week (subcutaneosly), 3 times for week, 300 IU/kg in each administration, in the right deltoid region. It will administer in patient hospitalized. If the premature infant have the minimal weight established (2500 g), the administration will be in ambulatory way.
Vitamin therapy (oral route): VitaminE (25 mg), Vitamin C (50 mg), Folic acid (1mg) and Multivitamin complex 6 dropes. This treatment will begin since 5 days of life, like appears in the protocol of the newborn that are low weight.
Ferric supplement (Ferrous fumarate) by oral route. Doses 4 mg/kg/day; allowed scale up 6 mg/kg/day, according oral tolerability, until premature infant take in 100 ml/kg/day of maternal milk and/or artifitial milk.
All treatments will finish when the patient reaches corrected gestational age of 40 weeks.
---------- Primary Outcome(s):
Transfusional requirement from red globules (Yes, No). Measurement time: at the end of treatment and 30 days after end of treatment.
---------- Key Secondary Outcomes:
Number of red globules transfusions required (total of transfusions of blood required by the patient). Measurement time: at the end of treatment and 30 days after end of treatment.
Hematological status: Hemoglobin (g/l) and Hematocrit (%). Time of measurement: baseline, 7, 15, 30 and 45 days of treatment, at the end of treatment and 30 days after end of treatment.
Adverse Events (AE). Measurement time: 7, 15, 30 and 45 days of treatment, at the end of treatment and 30 days after end of treatment.
- AE occurrence in the subject (Yes/No)
- AE description (name of the AE)
- AE duration (different between of start date and the end date of the AE)
- AE Intensity (Mild, Moderate, Severe)
- AE severity (Grave/Serious, Not Grave/ Not Serious)
- Attitude from study treatment (Without change, Modification of doses, Temporal withdrawal, Definitive withdrawal from treatment)
- AE outcome (Recovered, Improved, Sequelae, Persists, Death)
- Casualty related (1.Very probably, 2.Probably 3.Possible, 4.Improbably, 5.Not related 6.Not evaluate)
---------- Gender:
3. Both
---------- Minimun Age:
8 days of birth
---------- Maximun Age:
none
---------- Inclusion Criteria:
1.Preterm patients with weight ≤ 1500 g and gestational age <34 weeks(determined by the method of date of last menstrual period).
2.Patients whose parent or responsible family has given its consent for participation in the study in writing.
3.Patients with more than 7 days old.
4.Patients with an intake of at least 50 ml/kg/ day of milk and/or artificial.
---------- Exclusión criteria:
1.Patients with hemolytic or hemorrhagic disease.
2.Patients diagnosed with major congenital malformation requiring transfer to another department of Neonatology.
3.Patients with known hypersensitivity to products derived from cells above or hypersensitivity to human albumin.
---------- Type of Participant:
2. Patients
---------- Type of study:

1. Interventional
---------- Allocation:
3. N/A: single arm study.
---------- Masking:
1. Open.
---------- Control Group:
3. Uncontrolled
---------- Study Design:
1. Single Group
---------- Other Design:
---------- Purpose:
1. Treatment
---------- Phase:
7. Phase III
---------- Target Sample Size:
72
---------- First Name (Contact for Public Queries):
Patricia MD.
---------- Middle Name (Contact for Public Queries):
---------- Last Name (Contact for Public Queries):
Piedra
---------- Affiliation (Contact for Public Queries):
CIMAB SA.
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206 street e/19 and 21 No.1926 Atabey,Playa
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---------- Country (Contact for Public Queries):
Cuba
---------- Zip Code (Contact for Public Queries):
11600
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11600
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---------- Email Address (Contact for Scientific Queries):
patrip@cim.sld.cu

---------- Primary Register:
RPCEC
---------- Unique ID number:
RPCEC00000088
---------- Date of Registration in Primary Register:
22/10/2009 20:00
---------- Record Verification Date:
01/09/2009 20:00

Agregar un Comentario