Safety assessment of Granulocyte Colony Stimulating Factor:ior LeukoCIM in oncohematologic patients.Phase IV study.

---------- Public Title:
Safety assessment of Granulocyte Colony Stimulating Factor:ior LeukoCIM in oncohematologic patients.Phase IV study.
---------- Scientific Title:
Safety assessment of Granulocyte Colony Stimulating Factor:ior LeukoCIM in oncohematologic patients.Phase IV study.
---------- Secondary Identifying Numbers:
IIC RD-089
---------- 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:
Central State Control of Drug Quality(CECMED),Notification,24-075-07B
---------- Authorization Date:
24/09/2007 00:00
---------- Reference Number:
24-075-07B
---------- Countries of Recruitment:
Cuba
---------- Province of Principal Site:
Havana City
---------- Principal Clinical Site:
Medical Surgical Research Center(CIMEQ)
---------- Principal Investigator:
MD.Mario Wilford de Leon.Second degree specialist in Internal Medicine.
---------- Other Clinical Sites:
Havana City,Clinical Surgical Hospital Hermanos Ameijeiras,MD.Calixto Hernandez.First degree specialist in Hematology.
Havana City,Institute of Hematology and Immunology,MD.Carlos Hernandez Padron.Second degree specialist in Hematology.
Havana Ciy,National Institute of Oncology and Radiobiology,MD.Jesus de los Santos Reno.First degree specialist in Oncology.
Havana City,Willian Soler Hospital,MD.Caridad Verdecia Cañizares.Second degree specialist in Oncología.
Havana City,Pediatric Hospital Juan Manuel Márquez(JMM),MD.Orestes Chagues Leyva.First degree specialist in Hematology.
Pinar del Rio,Clinical Surgical Teaching Hospital Abel Santamaria Cuadrado,MD.Felipe Aponte Espinosa.First degree specialist in Hematology.
Pinar del Rio,Pediatric Hospital Pepe Portilla,MD.Barbara Iglesias Castillo.First degree specialist in

Oncology.
Pinar del Rio,Comandante Pinares Hospital,MD.Anadely Gámez Pérez.First degree specialist in Hematología.
Matanzas,Jose Ramon Tabranes Provincial Hospital,MD.Eduardo Santiesteban Álvarez.First degree specialist in Oncology.
Matanzas,Faustino Perez Hospital,MD.Nereida Álvarez Vega.First degree specialist in Hematology.
Cienfuegos,Gustavo Aldereguia Lima Provincial Hospital,MD.Julio Damaso Fernandez Aguila.Second degree specialist in Hematology.
Sancti Spiritus,Camilo Cienfuegos Provincial Hospital,MD.Jose Alberto Rondon Ayala.Second degree specialist in Oncology.
Villa Clara,Jose Luis Miranda Pediatric Hospital,MD.Tamara Cedre Hernandez.First degree specialist in Hematology.
Villa Clara,Hospital Arnaldo Milián Castro Hospital,MD.Rosa Oliday Ríos Jiménez.First degree specialist in Hematology.
Holguin,Octavio de la Concepcion y la Pedraja Hospital,MD.Ricardo Reyes Avilés.First degree specialist in Pediatrie.
Santiago de Cuba,Juan Bruno Zayas Hospital,MD.Lidia Clara Suárez Beyríes.First degree specialist in Hematology.
---------- Research Ethics Committees:
Havana City,Institute of Hematology and Inmunology,June 29 2007.
Havana City,National Institute of Oncology and Radiobiology,May 31 2007.
Havana City,Clinical Surgical Hospital Hermanos Ameijeiras,April 9,2008.
Havana City,Juan Manuel Marquez Pediatric Hospital,January 31,2008.
Havana City,Willian Soler Hospital,May 14,2007.
Havana City,Center For Surgical Research(CIMEQ),November 27,2006.
Pinar del Rio,Pepe Portilla Pediatric Hospital,May 9,2007.
Pinar del Rio,Comandante Pinares Hospital,May 16,2007.
Pinar del Rio,Abel Santamaria Hospital,Febrary 8,2007.
Matanzas,José Ramón López Tabranes Provincial Hospital,November 22,2006.
Matanzas,Faustino Perez Hospital,December 4,2006.
Cienfuegos,Gustavo Aldereguia Lima Provincial Hospital,December 26,2006.
Sancti Spiritus,Camilo Cienfuegos Hospital,December 14,2006.
Villa Clara,Arnaldo Milian Hospital,November 24,2006.
Villa Clara,Jose Luis Miranda Pediatric Hospital,December 28,2006.
Holguin,Octavio de la Concepcion y la Pedraja Hospital,May 28,2007.
Santiago de Cuba,Juan Bruno Zayas Hospital,October 4,2007.
---------- Recruitment Status:
4. Closed
---------- Date of First Enrollment:
07/04/2007 00:00
---------- Health Condition(s) or Problem(s) Studied.:
Neutropenia secondary to Chemotherapy and/or Radiotherapy in oncohematologic patients .
---------- Intervention(s):
Starting dose:LeukoCIM 5µg/Kg/day,subcutaneous.
Primary prophylaxis:LeukoCIM the 24-72h at the end of the QT or RT continuing daily for 7-10 days or up to the NAC regained equal or greater than 1.5 x 109 / L.
Secondary prophylaxis:Patient with neutropenic episodes in previous treatment cycles,was administered ior LeukoCIM 24-72 h at the end of the QT or RT continuing daily for 7-10 days or up to the NAC regained equal or greater than 1.5 x 109/L.
Treatment of febrile neutropenic episodes secondary cycles of QT and/or RT will begin administering the ior LeukoCIM once diagnosed febrile neutropenia (CAN ≤ 1 x 109/L)and for no fever episodes(CAN ≤ 0.5 x 109/L),continuing daily until the CAN recovered to values equal to or greater than 1.5 x 109/L. The treatment is not discontinued,a maximum of 21 days before treatment with ior LeukoCIM if NAC has not reached the value of 1.5 x 109/L.

---------- Primary Outcome(s):
Incidence of Adverse Events (AE) with a causal relationship (IOR LeukoCIM) likely or very likely, measurement time 21 days.
---------- Key Secondary Outcomes:
Recovery of the Absolute Neutrophil Count figures to ≥ 1.5 x 109/L,was assessed using the dichotomous answer yes/no, 21 days measurement time.
Time of rercovery the Absolute Neutrophil Count figures to ≥ 1.5 x 109/L, will be assessed on days 21 days measurement time.
Biochemical parameters, the values recorded by the units set for each measurement time 21 days.
Occurrence of any adverse event was evaluated by yes/no, measurement time: 21 days.
Duration of adverse events was assessed in hours and days, measuring time: 21 days.
Intensity of adverse events, Light, Moderate, Severe, Very Severe, measurement time: 21 days
Result, recovered, improved, or persisted Secuelas, measurement time: 21 days
Attitude to treatment, no change, modification of dose or temporary interruption final measurement time: 21 days
Causal relationship, very likely, likely, possible, remote, measurement time:21 days
---------- Gender:
3. Both
---------- Minimun Age:
None
---------- Maximun Age:
None
---------- Inclusion Criteria:
1.Patients who met the diagnostic criteria and/or condition of use.
2.Patients with cytologic diagnosis and/or histologically confirmed cancer of any location that are receiving QT and/or RT.
3.Patients of all ages and both sexes.
---------- Exclusión criteria:
1.Patients with known hypersensitivity to products derived from cells of E.Coli or other preparations of rG-CSF.
2.Patients pregnant or breastfeeding.
---------- 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:
8. Phase IV
---------- Target Sample Size:
Inclusion of 2 years,sample size is not calculated. Included 914 episodes
---------- First Name (Contact for Public Queries):
MD.Patricia
---------- Middle Name (Contact for Public Queries):
---------- Last Name (Contact for Public Queries):

Piedra
---------- Affiliation (Contact for Public Queries):
CIMAB S.A
---------- Postal Address (Contact for Public Queries):
206 No.1926 e/19 and 21 Atabey ,Playa
---------- City (Contact for Public Queries):
Havana City
---------- Country (Contact for Public Queries):
Cuba
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11600
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Havana City
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Cuba
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patrip@cim.sld.cu
---------- Primary Register:
RPCEC
---------- Unique ID number:
RPCEC00000083
---------- Date of Registration in Primary Register:
24/07/2009 20:00
---------- Record Verification Date:
20/07/2009 20:00

Agregar un Comentario