Effectiveness and Safety of ior EPOCIM in patients with Chronic Renal Failure on dialysis methods.

---------- Public Title:
Effectiveness and Safety of ior EPOCIM in patients with Chronic Renal Failure on dialysis methods.
---------- Scientific Title:
Effectiveness and Safety of ior EPOCIM in patients with Chronic Renal Failure on dialysis methods (hemodialysis or peritoneal dialysis).
---------- Secondary Identifying Numbers:
IIC RD-091
---------- 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),Notification,24-076-07-B
---------- Authorization Date:
03/08/2007 00:00
---------- Reference Number:
24-076-07-B
---------- Countries of Recruitment:
Cuba
---------- Province of Principal Site:
Havana City
---------- Principal Clinical Site:
National Institute of Nephrology.
---------- Principal Investigator:
MD.Jorge F.Pérez-Oliva Díaz.Second degree specialist in Nephrology.
---------- Other Clinical Sites:
Havana City,Hermanos Ameijeiras Hospital,MD.Amaury Lorenzo Clemente.Second degree specialist in Nephrology.
Havana City,Miguel Enríquez Hospital,MD.Randolfo Torres Martínez.First degree specialist in Nephrology.
Pinar Del Rio,Abel Santamaría Hospital,MD.Félix Eduardo Lugo López.First degree specialist in Nephrology.
Villa Clara,Arnaldo Milián Hospital,MD.Eduviel Ramos Cárdenas.First degree specialist in Nephrology.
---------- Research Ethics Committees:
Havana City,Hermanos Armeijeiras Hospital,December 20,2006.
Havana City,National Institute of Nephrology,December 21,2006.
Habana City,Miguel Enrique Hospital,January 19,2007.
Pinar del Rio,Abel Santamaria Hospital,March 15,2007.
Villa Clara,Arnaldo Milian Hospital,Febrary 12,2007.
---------- Recruitment Status:
4. Closed

---------- Date of First Enrollment:
01/03/2007 00:00
---------- Health Condition(s) or Problem(s) Studied.:
Chronic Renal Insufficiency.
---------- Intervention(s):
EPOCIM:25-200 IU/kg(subcutaneously)3 times per week for 12 months.
---------- Primary Outcome(s):
Hemoglobin(g/dl), Hematocrit(%), Assessment of response (Optimal, Good, Fair, Poor), Response Type (Maintain, Increase, Decrease). Measurement time: 12 months.
---------- Key Secondary Outcomes:
Biochemical parameters:The values recorded by the units set for each,measurement time:12 months.
Occurrence of any adverse event in the subject:yes/no,measurement time:12 months.
Duration of the adverse event:Dates of commencement and completion of the adverse event,measurement time:12 months.
Intensity of adverse event:Slight,Moderate,Severe,Very severe,measurement time:12 months.
Causal relationship:Very likely, likely, possible, remote,measurement time:12 months.
Attitude to treatment:No change, modification of dosage, temporary interruption final,measurement time:12 months.
Result of the treatment applied to counter adverse event:Recovered,Improved,sequelae persists,measurement time:12 months.
Indicators of Quality of Life,will assess the improvement of the parameters of quality of life through Fact-An Inquiry,measurement time:12 months.
---------- Gender:
3. Both
---------- Minimun Age:
18 years
---------- Maximun Age:
none
---------- Inclusion Criteria:
1.Patients with inform consent signed.
2.Patients with stable dialysis treatment at least of 3 months prior.
3.Patients who are receiving ior EPOCIM for the treatment of anemia associated with CRF.
4.Age less than 18 years.
5.To be included in the study patients of both sexes.
---------- Exclusión criteria:
1.Patients with known hypersensitivity to products derived from cells above or hypersensitivity to human albumin.
2.Patients pregnant or breastfeeding.
---------- Type of Participant:
2. Patients
---------- Type of study:
1. Interventional
---------- Allocation:
2. Nonrandomized Trial
---------- Masking:
1. Open.
---------- Control Group:
3. Uncontrolled
---------- Study Design:
1. Single Group
---------- Other Design:
---------- Purpose:
1. Treatment
---------- Phase:

8. Phase IV
---------- Target Sample Size:
621
---------- 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
---------- Zip Code (Contact for Public Queries):
11600
---------- Telephone (Contact for Public Queries):
(537)271-50-57 Ext.111
---------- Email Address (Contact for Public Queries):
patrip@cim.sld.cu
---------- First Name (Contact for Scientific Queries):
MD.Patricia
---------- Middle Name (Contact for Scientific Queries):
---------- Last Name (Contact for Scientific Queries):
Piedra
---------- Affiliation (Contact for Scientific Queries):
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Cuba
---------- Zip Code (Contact for Scientific Queries):
11600
---------- Telephone (Contact for Scientific Queries):
(537)271-50-57 Ext.111
---------- Email Address (Contact for Scientific Queries):
patrip@cim.sld.cu
---------- Primary Register:
RPCEC
---------- Unique ID number:
RPCEC00000082
---------- Date of Registration in Primary Register:
10/07/2009 20:00
---------- Record Verification Date:
06/07/2009 20:00

Agregar un Comentario