Effect and Safety of ior® EPOCIM in patients with Non-Hodking Lymphoma treated with anthracyclines.

---------- Public Title:
Effect and Safety of ior® EPOCIM in patients with Non-Hodking Lymphoma treated with anthracyclines.
---------- Scientific Title:
Evaluation of the Effect and Safety of ior® EPOCIM use in the prevention of cardiotoxicity in patients with Non-Hodking Lymphoma treated with anthracyclines.
---------- Secondary Identifying Numbers:
IIC-RD EC126
---------- Issuing Authority of the Secondary Identifying Numbers:
Center of Molecular Inmunology
---------- Primary Sponsor:
Center of Molecular Inmunology
---------- Secondary Sponsor(s):
No proceed
---------- Source(s) of Monetary or Material Support:
State Reserve
---------- Regulatory authority to approve the initiation to the study:
Center for State Control of the Quality of Drugs.
---------- Authorization Date:
26/02/2010 00:00
---------- Reference Number:
246/05.024.09.B
---------- Countries of Recruitment:
Cuba
---------- Province of Principal Site:
Cienfuegos
---------- Principal Clinical Site:
Gustavo Aldereguía Lima Hospital
---------- Principal Investigator:
Liermis Michael Dita Salabert,MD.First degree specialist in Hematology.
Rafael Gómez Baute,MD.First degree specialist in Hematology and GMI.
---------- Other Clinical Sites:
Havana City,Hermanos Ameijeiras Hospital,Aramis Núñez Quintana,MD.First degree specialist in Hematology.
---------- Research Ethics Committees:
Havana City,Hermanos Ameijeiras Hospital,october 05,2009.
Cienfuegos,Gustavo Aldereguía Lima Hospital,july 15,2009.
---------- Recruitment Status:
1. Pending
---------- Date of First Enrollment:
19/05/2010 00:00
---------- Health Condition(s) or Problem(s) Studied.:
Patients with Non-Hodking Lymphoma
---------- Intervention(s):
Experimental group:Treatment with 2 doses of ior® EPOCIM 40 000 IU each.
The study drug will be administered intravenously, diluted in 100 ml of dextrose 5 % or saline infusion

0.9% for 30 minutes.The first dose will be administered 1 hour before infusion of doxorubicin.The second dose will be administered 24 hours after infusion of doxorubicin.
The treatment with ior® EPOCIM will be repeated in each cycle of chemotherapy the patient receive (between 6 and 8).
Control Group: Not receive treatment with ior® EPOCIM.
All patients will receive the scheme CHOP (cyclophosphamide (C),doxorubicin (H),vincristine (O),prednisone (P))every 14,21,ó 28 days,dependent of clinical conditions of the patient and his treatment response,until 6 or 8 cycles .It´s considering 450 mg accumulative doxorubicin dose.
---------- Primary Outcome(s):
Diastolic dysfunction (Yes/No).Dependent of the Deceleration time (DT),the value ejection/shortening (E/A)and the Isovolumic relaxation time (IVRT).
Measurement time:in each cycle of chemotherapy ,4 weeks after finish chemotherapy , and every 4 months for a year after finish treatment .
---------- Key Secondary Outcomes:
Related to the effect:
- Systolic function using the ejection fraction of left ventricular (LVEF)and the fractional shortening (FAC)
- Isovolumetric ejection total index (TEI index)
- Apearance of clinical signs and symptoms associated cardiotoxicity (description of the symptoms)
- Time to onset of cardiotoxic event(days between inclusion date and date of the event if it appears)
- Hemoglobin using units establish in clinical sites
- Hematocrit using units establish in clinical sites
- Ventricular diameter (diastolic and systolic)in mm
- Interventricular septum diameter (diastolic and systolic) in mm
- Posterior wall diameter (diastolic and systolic) in mm
- Atrial diameter (systolic)in mm
Measurement time :in each cycle of chemotherapy ,4 weeks after finish chemotherapy ,and every 4 months for a year after finish treatment.
- Heart damage enzyme(Fraction M/B of the CPK,Troponin I & II).Measurement time:after finish the chemotherapy.
Related Safety:
Occurrence of some adverse events (AE)in the subject.
-Description of AE.Name of the event
-Duration of AE.(Difference between the beginning date and the finish date of the event)
-Intensity of AE (Slight , Moderate, Severe)
-Severity of AE (Severe/Serious,Not severe/Not serious)
-Attitude to study treatment (Unchanged,Dose modification ,Temporary discontinuation of study treatment,Permanent discontinuation of study treatment)
-Outcome of AE (Recovered,Improved,Persist,Persist,Sequelae)
-Relationship causality (Definitive,Very likely,Probable,Possible,Not related,Unknown)
-Onco-specific Treatment response (CHOP)(Complete Response ,Partial Response,No response ,Resistance/Progressive Disease)
Measurement time:in each cycle of chemotherapy,4 weeks after finish chemotherapy and every 4 months for a year after finish treatment.
---------- Gender:
3. Both
---------- Minimun Age:
18 years
---------- Maximun Age:
N/A(No limit)
---------- Inclusion Criteria:
.Patients who met the diagnostic criteria.
.Patients of either sex with age greater than or equal to 18 years.
.Patients who give informed consent to participate in writing.

.Patients with hemoglobin below 15 g/dl.
---------- Exclusión criteria:
.Patients with uncontrolled hypertension.
.Patients with known risk or a history of venous or arterial thromboembolic disease.
.Severe cardiovascular disease:unstable angina,heart failure,aortic stenosis,endocarditis.
.Patients with poor acoustic window.
.Severe cerebrovascular disease.
.Septic embolism.
.Chronic myeloproliferative diseases.
.Patients with known hypersensitivity to products derived from higher cells or hypersensitivity to human albumin.
---------- Type of Participant:
2. Patients
---------- Type of study:
1. Interventional
---------- Allocation:
1. Randomized Controlled Trial
---------- Masking:
1. Open.
---------- Control Group:
2. Active
---------- Study Design:
5. Other
---------- Other Design:
Fleming Secuencial Desing (two stages)
---------- Purpose:
1. Treatment
---------- Phase:
5. Phase II
---------- Target Sample Size:
88
---------- First Name (Contact for Public Queries):
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RPCEC
---------- Unique ID number:
RPCEC00000096
---------- Date of Registration in Primary Register:
11/06/2010 20:00
---------- Record Verification Date:
19/05/2010 20:00

Agregar un Comentario