EPOCIM in benign prostatic hyperplasia.

---------- Public Title:
EPOCIM in benign prostatic hyperplasia.
---------- Scientific Title:
Efficacy and safety of ior EPOCIM in reducing transfusion requirements in elective surgical patients with benign prostatic hyperplasia.
---------- Secondary Identifying Numbers:
IIC RD-EC096
---------- 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:
23/12/2008 00:00
---------- Reference Number:
009/05.011.08.B
---------- Countries of Recruitment:
Cuba
---------- Province of Principal Site:
Santiago of Cuba
---------- Principal Clinical Site:
Saturnino Lora Provincial Hospital
---------- Principal Investigator:
MD.Arístides de Jesús Luna González.Second degree specialist in Anesthesiology and Medical Reanimación.Instructor.MsC.Urgencias.
---------- Other Clinical Sites:
Havana City,Enrique Cabrera Hospital,MD.Roberto Milián Echavarría.First degree specialist in Urology.
Havana City,Joaquín Albarrán Hospital,MD.Alberto Elejalde Hernández.First degree specialist in Urology.
Havana City,Calixto García Hospital,MD.Osvaldo Cantero.First degree specialist in Urology.
Villa Clara,Arnaldo Milián Castro Hospital,MD.Julio Vigil Quiñones.Second degree specialist in Urology.
Camagüey,Manuel Ascunce Domenech Hospital,MD. Juan Carlos Yip Felipe.First degree specialist in Urology.
Camagüey,María Curie Hospital,MD.Ranfis Rodríguez Bueno.First degree specialist in Urology.
Guantánamo,Agostinho Neto Hospital,MD.Gervasio Turcaz Alcolea.First degree specialist in Urology.
Santiago de Cuba,Juan Bruno Zayas General Hospital,MD.Santiago Duchases Olivares.First degree specialist in Urology.
---------- Research Ethics Committees:
Havana City,Enrique Cabrera Hospital,October 17,2008.
Havana City,Hospital Joaquín Albarrán Hospital,October 22,2008.
Havana City,Calixto García Hospital,October 22,2008.

Villa Clara,Arnaldo Milián Castro Hospital,March 9,2009.
Camagüey,Manuel Ascunce Domenech Hospital,January 14,2009.
Camagüey,María Curie Hospital,October 14,2008.
Guantánamo,Agostinho Neto Hospital,December 22,2008.
Santiago of Cuba,General Juan Bruno Zayas Hospital,June 28,2008.
Santiago of Cuba,Provincial Saturnino Lora Hospital,June 20,2008.
---------- Recruitment Status:
2. Active
---------- Date of First Enrollment:
15/05/2009 00:00
---------- Health Condition(s) or Problem(s) Studied.:
Benign prostatic hyperplasia
---------- Intervention(s):
Experimental group:
- EPOCIM 40 000 IU (Bulbs 10 000 IU), subcutaneous (sc). A single dose weekly, prior to the scheduled date for surgery on days -21,-14,-7 and -1)
- Oral supplement of ferrous fumarate, folic acid and polivit. Daily from day -21 to -1 before surgery.
Control group:
- Oral supplement of ferrous fumarate, folic acid and polivit. Daily from day - 21 to -1 before surgery.
Ferrous fumarate (200 mg). One tablet daily away from meals
Folic acid (5 mg). One tablet daily.
Polivit. One tablet daily.
---------- Primary Outcome(s):
- Need for transfusion requirements (yes/no). Measuring time: three days after surgery
---------- Key Secondary Outcomes:
- Transfusion required (number of transfusions of blood that the patient required). Measurement Time: three days after surgery.
- Hematological status (hemoglobin and hematocrit with the values recorded by the units in each institution). Measurement Time: days -21,-14,-7 and -1 before surgery and +1,+3 after surgery.
- Hemodynamic status (blood pressure in mmHg and heart rate in beats/min). Measuring time: days -21,-14,-7 and -1 before surgery and +1, +3 after surgery.
Adverse events (AE). Measurement time: three days after surgery.
- Occurrence of AE (yes, no)
- Description of AE (name of the adverse event is presented)
- Duration of AE (difference between the start date and the end date of AE in minutes, hours or days)
- Intensity of AE (1.Mild, 2.Moderate, 3.Severe, 4.Grave that the death of the subject, 5.Grave which threatens the life of the subject, 6.Grave requiring/prolonging hospitalization, 7.Grave producing disability/ significant disability or persistent, 8.Grave birth defect or congenital anomaly)
- Severity of AE (Grave/serious, not Grave/not serious)
- Attitude to the study treatment (unchanged, dose modification, temporary discontinuation of study treatment, permanent discontinuation of study treatment)
- Result of AE (recovered, improved, persist, sequelae)
- Causal link (1.Ultimately, 2.Very likely, 3.Likely, 4.Possible, 5.Not related, 6.Unknown)
---------- Gender:
2. Male
---------- Minimun Age:
19 years
---------- Maximun Age:
none
---------- Inclusion Criteria:
1.Patients who fulfill the diagnostic criteria.
2.Patients older than 18 years.
3.Patients give their informed consent to participate in writing.
---------- Exclusión criteria:

1.Uncontrolled hypertension.
2.Patients with known risk or a history of arterial or venous thromboembolic disease.
3.Severe cardiovascular disease: unstable angina, heart failure, aortic stenosis.
4.Severe vascular brain disease.
5.Known infectious diseases such as HIV/AIDS,Hepatitis B and C.
6.Patients with known hypersensitivity to products derived from cells above or hypersensitivity to human albumin.
7.Hematologic Diseases:Sicklemia,Myelodysplastic syndromes,Disorders of coagulation.
8.Surgical approach to patients with benign prostatic hyperplasia by transurethral.
---------- Type of Participant:
2. Patients
---------- Type of study:
1. Interventional
---------- Allocation:
1. Randomized Controlled Trial
---------- Masking:
1. Open.
---------- Control Group:
2. Active
---------- Study Design:
2. Parallel
---------- Other Design:
---------- Purpose:
1. Treatment
---------- Phase:
7. Phase III
---------- Target Sample Size:
306
---------- First Name (Contact for Public Queries):
MD.Giselle
---------- Middle Name (Contact for Public Queries):
---------- Last Name (Contact for Public Queries):
Saurez
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Havana City
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Cuba
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(537)271-50-57 Ext.111
---------- Email Address (Contact for Scientific Queries):
giselle@cim.sld.cu
---------- Primary Register:
RPCEC
---------- Unique ID number:
RPCEC00000092
---------- Date of Registration in Primary Register:
23/10/2009 20:00
---------- Record Verification Date:
28/08/2009 20:00

Agregar un Comentario