Effectiveness and Safety of Nimotuzumab for the treatment of patients with glial tumors

---------- Public Title:
Effectiveness and Safety of Nimotuzumab for the treatment of patients with glial tumors
---------- Scientific Title:
Evaluation of the Effectiveness and Safety of Monoclonal Antibody HR3(Nimotuzumab)for the treatment of patients with glial tumors of high grade malignancy.
---------- Secondary Identifying Numbers:
IIC RD-EC0114
---------- Issuing Authority of the Secondary Identifying Numbers:
Center of Molecular Inmunology(CIM)
---------- Primary Sponsor:
Center of Molecular Inmunology(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,04-076-08B
---------- Authorization Date:
16/09/2008 00:00
---------- Reference Number:
04-076-08B
---------- Countries of Recruitment:
Cuba
---------- Province of Principal Site:
Havana City
---------- Principal Clinical Site:
Center for Research Surgical Medical(CIMEQ)
---------- Principal Investigator:
PhD.Javier Figueredo (MD),Second degree specialist in Neurosurgery.
---------- Other Clinical Sites:
Havana City,Hermanos Ameijeiras Hospital,MD.Silvia Noema Salva.Second degree specialist in Neurosurgery.
Havana City,Nacional Institute of Oncology and Radiobiology,MD.Daysi Chi Ramirez,First degree specialist in Neurology,Second degree specialist in Oncology.
Havana City,Carlos J.Finlay Hospital,MD.Víctor Dubois.Second degree specialist in Neurosurgery.
Havana City,Calixto García Universitary Hospital,MD.Maria Teresa Solomon Cardona,First degree specialist in Neurosurgery.
Pinar del Río,Congress Three Hospital,MD.Bárbara Iglesias Hernández.First degree specialist in Oncology.
Matanzas,José R.López Tabranes Hospital,MD.Rafael Guerra Sanchez,First degree specialist in Neurosurgery.
Villa Clara,Arnaldo Milián Hospital,MD.Jose E.Vaquer Fernandez.First degree specialist in Neurosurgery.
Villa Clara,Celestino Hernández Robau Universitary Hospital,MD.Julio Orlando Hernandez Cruz.First degree specialist in Oncology.
Camaguey,Maria Curié Oncology Hospital,MD.Carolina Toledo Jimenez,First degree specialist in

Oncology.
Holguín,Lucía Iñiguez Landin Surgical-Medical Hospital,MD.Julio Cesar Selva Infantes.Second degree specialist in Neurosurgery.
Santiago de Cuba,Saturnino Lora Torres Surgical-Medical Hospital,MD.Rafael Domínguez Peña.First degree specialist in Neurosurgery.
---------- Research Ethics Committees:
Havana City,Center for Research Surgical Medical,July 1,2008.
Havana City,Hermanos Ameijeiras Hospital,September 15,2008.
Havana City,Nacional Institute of Oncology and Radiobiology,June 29,2009.
Havana City,Carlos J.Finlay Hospital,January 22,2009.
Havana City,Calixto Garcia Universitary Hospital,May 14,2009.
Pinar del Río,Congress Three Hospital,June 30,2008.
Matanzas,José R.López Tabrane Hospital,April 22,2009.
Villa Clara,Arnaldo Milián Castro Hospital,November 14,2008.
Villa Clara,Universitary Hospital MD.Celestino Hernandez Robau,March 16,2009.
Camaguey,Maria Curié Hospital,October 13,2008.
Holguin,Lucia Iñiguez Landin Clinical-Surgical Hospital,September 29,2008"
Santiago de Cuba,Saturnino Lora Torres Provincial Hospital,July 29,2008
---------- Recruitment Status:
2. Active
---------- Date of First Enrollment:
30/09/2008 00:00
---------- Health Condition(s) or Problem(s) Studied.:
Glial Tumors of High grade of Malignancy (Glial Cell Tumors).
---------- Intervention(s):
Nimotuzumab: 200 mg intravenous (antecubital vein) in a volume of 250 ml (complete with saline) infusion for one hour.
Induction Phase: 200mg (once per week) for 6 weeks. If the patient is newly diagnosed, this treatment will be received concomitant with radiation therapy (RT). If after 15 days of surgery, is not possible to begin the RT, treatment with Nimotuzumab will begin, and the induction phase will continue until the end of RT.
Radiotherapy (RT):1.8-2Gy daily, split into 5d/week (Monday-Friday). Total dose: between 50 and 60Gy for 5-6 weeks.
Maintenance and consolidation phase: One time every 14 days until the patient's deterioration from the disease or toxicity not tolerated.
---------- Primary Outcome(s):
Global Survival. Time (in months) from inclusion date to death or last date you have news.
Measurement time: From the inclusion date to the date of death or last date there is news.
---------- Key Secondary Outcomes:
Adverse Events (AE). Measuring Time: in every administration of the product. It is compound by:
-Description of AE (name of AE)
-Intensity of AE (Grade 1: Mild, Grade 2: Moderate, Grade 3: Severe, Grade 4: Danger to life, Grade 5: Death)
-Causation of AE (very likely causality, likely Causality, possible Causality, not related, Unknown)
Objective antitumor response evaluated using MacDonald criteria (Complete response, partial response, progressive disease, stable disease). Measurement Time: Prior to inclusion in the clinical trial, at week 8 and every 3 months to 24 months.
Progression-free survival (PFS). Time between the start of treatment at the date of clinical progression or imaging/last scheduled visit when there is news of the patient/or date of death. Measuring Time: since the start of treatment at the last scheduled visit when there is news of the patient/or date of death.
---------- Gender:
3. Both
---------- Minimun Age:

18 years
---------- Maximun Age:
none
---------- Inclusion Criteria:
1.Patients with glials tumors grade III or IV confirmed by pathology techniques,which at the time of inclusión are candidates for onco-specific treatment or patients with the same diagnosis who are relapsed.
2.Age ≥ 18 years of both sexes.
3.General health status according to Karnofsky index ≥ 50.
4.Laboratory parameters within normal limits defined as:Hematopoietic:Hemoglobin ≥ 9 g/L,total leukocytes count ≥ 3 x 109 cells/L,platelets ≥ 100 x 109/L Hepatic:hepatic function within 2.5 times upper limit of normal and without liver diseases demonstrated by TGP and TGO alkaline phosphatase.
5.Patients express written voluntary entry into the study by signing the document informed consent.
6.Patients of childbearing age should have a negative pregnancy test and used effective methods of contraception such as IUDs,hormonal contraceptives, barrier method or tubal ligation.
---------- Exclusión criteria:
1.Pregnancy or lactation.
2.Patients with a concomitant second tumor.
3.Submit a chronic disease associated in decompensated phase(heart disease,diabetes,hypertension).
4.History of hypersensitivity to other similar product.
5.Severe acute allergic states.
6.Fever.
7.Severe septic processes.
---------- 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.
---------- 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
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206 No.1926 e/19 and 21 Atabey,Playa
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---------- Country (Contact for Public Queries):

Cuba
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11600
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patrip@cim.sld.cu
---------- First Name (Contact for Scientific Queries):
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Piedra
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(537)271 50-57 Ext.111
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patrip@cim.sld.cu
---------- Primary Register:
RPCEC
---------- Unique ID number:
RPCEC00000087
---------- Date of Registration in Primary Register:
18/09/2009 20:00
---------- Record Verification Date:
24/08/2009 20:00

Agregar un Comentario