Clinical trial, phase II, to evaluate rhEGF efficacy and safety at a dose of 25 or 75 micrograms intralesionally in patients with diabetic foot ulcer (Wagner grade 1 or 2).

---------- Public Title:
Clinical trial, phase II, to evaluate rhEGF efficacy and safety at a dose of 25 or 75 micrograms intralesionally in patients with diabetic foot ulcer (Wagner grade 1 or 2).
---------- Scientific Title:
Phase II, multi-centered, randomized, double-blind, placebo-controlled clinical trial to evaluate efficacy and safety of recombinant human Epidermal Growth Factor (rhEGF) at a dose of 25 or 75 micrograms intralesionally 3 times a week for up to 12 weeks, in patients with diabetic foot ulcer (Wagner grade 1 or 2).
---------- Secondary Identifying Numbers:
IG/FCEI/PD/0708
---------- Issuing Authority of the Secondary Identifying Numbers:
Center for Genetic Engineering and Biotechnology (CIGB), Havana City
---------- Primary Sponsor:
Center for Genetic Engineering and Biotechnology (CIGB), Havana City
---------- Secondary Sponsor(s):
Praxis Pharmaceutical.
---------- Source(s) of Monetary or Material Support:
Center for Genetic Engineering and Biotechnology (CIGB)
Praxis Pharmaceutical.
---------- Regulatory authority to approve the initiation to the study:
Center for State Control of the Quality of Drugs (CECMED)
---------- Authorization Date:
02/01/2008 18:00
---------- Reference Number:
---------- Countries of Recruitment:
Cuba
---------- Province of Principal Site:
Havana City
---------- Principal Clinical Site:
National Center of Toxicology (CENATOX)
---------- Principal Investigator:
Dr. Jose Fernandez Montequin.
---------- Other Clinical Sites:
Havana City, CIMEQ, Dr. Carlos Rodriguez Valdes-Fauly.
---------- Research Ethics Committees:
National Center of Toxicology (CENATOX), august 21 2007
Surgical Medical Research Center, October 11, 2007
---------- Recruitment Status:
1. Pending
---------- Date of First Enrollment:
04/10/2008 20:00
---------- Health Condition(s) or Problem(s) Studied.:
Patients with diabetic foot ulcer (Wagner grade 1 or 2).
---------- Intervention(s):
One bulb (75 ug, 25 ug or placebo, as appropriate) will be administered intralesionally 3 times a week until lesion occlusion or for up to 12 weeks. Bulb reconstitution and dilution will be performed using 5

mL of injection water. The product will be spread over the lesion applying 0.5 - 1 mL during each infiltration. When lesion size gets smaller than 1 cm2, the number of injections and the volume to be administered will be determined by researcher, depending on lesion size and resistance.
---------- Primary Outcome(s):
One bulb (75 ug, 25 ug or placebo, as appropriate) will be administered intralesionally 3 times a week until lesion occlusion or for up to 12 weeks. Bulb reconstitution and dilution will be performed using 5 mL of injection water. The product will be spread over the lesion applying 0.5 - 1 mL during each infiltration. When lesion size gets smaller than 1 cm2, the number of injections and the volume to be administered will be determined by researcher, depending on lesion size and resistance.
---------- Key Secondary Outcomes:
Total lesion occlusion at 4th, 8th, 16th, and 20th weeks.
Time required for total lesion occlusion.
Occlusion in 50% of the initial ulcer area. The number of patients exhibiting 50% of ulcer occlusion at 4th, 8th, 12th, 16th, and 20th weeks will be determined.
Time required for 50% lesion occlusion.
Development of granular tissue in 90% of lesion area. The number of patients exhibiting this effect at 4th and 8th weeks will be determined. When lesion area is reduced, the granulated and occluded areas are added up, and the percentage based on the area measured before applying the product is calculated.
Time required for granular tissue formation in 90% of ulcer area.
Systemic EGF concentration after intralesional application.
---------- Gender:
3. Both
---------- Minimun Age:
18 years
---------- Maximun Age:
No limit
---------- Inclusion Criteria:
1) Patients with DM type 1 or 2 under ADA criteria.
2) Patients of both sexes, aged >= 18.
3) Diabetic foot ulcers classified by Wagner as grade 1 covering an area >10 and =50 cm2 or grade 2 covering an area >1 and =50 cm2.
4) Neuropathic ulcer evidenced by palpable distal pulses and ankle/arm index (AA/I) = 0.8 and < 1.3. If arterial calcification occurs (AA/I = 1.3), the finger/arm index (FA/I) will be used. It should not exceed 0.7.
5) Ulcer = 4 week evolution.
6) Reproductive age men and women should use effective contraceptive methods for up to three months after completing treatment.
7) Patients should give their consent.
---------- Exclusión criteria:
1. Infection signs or symptoms.
2. Osteomyelitis or ulcers with bone exposure.
3. Poorly controlled diabetes mellitus (Hb A1c > 10%).
4. Connective tissue diseases.
5. Use of drugs likely to interfere with (corticoids or inmunosuppressors) or to favor cicatrisation (pentoxifylline, prostaglandin and other growth factors) in the previous 3 weeks.
6. Uncontrolled systemic or serious diseases: cardiopathies (acute myocardial infarction < 3 months, unstable angina or heart failure with edema), moderate or serious liver failure, kidney failure with serum creatinine values > 200mmol/L.
7. Clinical malnutrition signs or albumin levels < 30 g/L.
8. Hemoglobin < 100g/L.
9. Hypersensitivity to the product or any of its components.
10. History of current or past neoplasia.
11. Failure to conduct relevant evaluations or keep appropriate drainage in affected limb.
12. Previous intralesional EGF treatment in current lesion or < 4 weeks in any other lesion, or topical EGF < 4 weeks in current lesion.
13. Psychiatric or neurological diseases preventing informed consent.

14. History of alcoholism or drug addiction one year prior to inclusion.
15. Pregnancy or breastfeeding.
---------- Type of Participant:
2. Patients
---------- Type of study:
1. Interventional
---------- Allocation:
1. Randomized Controlled Trial
---------- Masking:
3. Double Blind
---------- Control Group:
1. Placebo
---------- Study Design:
2. Parallel
---------- Other Design:
---------- Purpose:
1. Treatment
---------- Phase:
5. Phase II
---------- Target Sample Size:
132
---------- First Name (Contact for Public Queries):
Dr. Blas
---------- Middle Name (Contact for Public Queries):
Yamir
---------- Last Name (Contact for Public Queries):
Betancourt Rodriguez.
---------- Affiliation (Contact for Public Queries):
Center for Genetic Engineering and Biotechnology. (CIGB)
---------- Postal Address (Contact for Public Queries):
Ave 31 / 158 y 190. Cubanacan Playa
---------- City (Contact for Public Queries):
Havana City
---------- Country (Contact for Public Queries):
Cuba
---------- Zip Code (Contact for Public Queries):
---------- Telephone (Contact for Public Queries):
(53-7)- 2087379
---------- Email Address (Contact for Public Queries):
blas.yamir@cigb.edu.cu
---------- First Name (Contact for Scientific Queries):
Blas
---------- Middle Name (Contact for Scientific Queries):
Yamir
---------- Last Name (Contact for Scientific Queries):
Betancourt Rodriguez.
---------- Affiliation (Contact for Scientific Queries):
Center for Genetic Engineering and Biotechnology. (CIGB)
---------- Postal Address (Contact for Scientific Queries):
Ave 31 / 158 y 190. Cubanacan Playa
---------- City (Contact for Scientific Queries):
Havana City
---------- Country (Contact for Scientific Queries):
Cuba
---------- Zip Code (Contact for Scientific Queries):
---------- Telephone (Contact for Scientific Queries):

(53-7)- 2087379
---------- Email Address (Contact for Scientific Queries):
blas.yamir@cigb.edu.cu
---------- Primary Register:
RPCEC
---------- Unique ID number:
RPCEC00000048
---------- Date of Registration in Primary Register:
24/12/2010 18:00
---------- Record Verification Date:
07/03/2008 18:00
Next Update Date:
03/09/2008 20:00
DIRECTIONS: Please, fill the data distributed in tabs. Use the “Next” and “Previous” buttons to switch tabs and the “Save” button to store form data. Click in the “Next” button to begin filling the form.:
Agregar un Comentario