Pharmacokinetics in intralesional administration of recombinant Epidermal Growth Factor in patients with diabetic foot ulcers.

---------- Public Title:
Pharmacokinetics in intralesional administration of recombinant Epidermal Growth Factor in patients with diabetic foot ulcers.
---------- Scientific Title:
Pharmacokinetics in intralesional administration of recombinant Epidermal Growth Factor in patients with diabetic foot ulcers.
---------- Secondary Identifying Numbers:
IG/FCEI/PD/0707.
---------- 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:
15/10/2007 20:00
---------- Reference Number:
1882/05-021-07-B
---------- 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:
Not applicable
---------- Research Ethics Committees:
National Center of Toxicology (CENATOX), august 21, 2007
---------- Recruitment Status:
4. Closed
---------- Date of First Enrollment:
19/11/2007 18:00
---------- Health Condition(s) or Problem(s) Studied.:
Health Condition(s) or Problem(s) Studied:
Diabetic foot ulcer, Wagner grades 1 or 2.
---------- Intervention(s):
Group I. EGF-75 µg, administered intralesionally 3 times a week until lesion size is reduced to 1 cm2 or for up to 12 weeks.
Group II. EGF-75 µg, administered intralesionally 3 times a week until lesion size is reduced to 1 cm2 or

for up to 12 weeks.
Group III. Placebo, administered intralesionally 3 times a week until lesion size is reduced to 1 cm2 or for up to 12 weeks. EGF bulb reconstitution and dilution will be performed using 5 mL of injection water.
---------- Primary Outcome(s):
Basal EGF plasma concentration; 5, 15, 30, 45 and 60 minutes after first and last applications, and 1.5, 2, 3, 4, 6, 8, 12, 24, 36 and 48 hours after first and last applications.
---------- Key Secondary Outcomes:
Ratio of patients with total occlusion 12 weeks after commencing treatment.
---------- Gender:
3. Both
---------- Minimun Age:
18 years
---------- Maximun Age:
70 years
---------- Inclusion Criteria:
1. Patients with DM type 1 or 2 under ADA criteria.
2. Patients of both sexes, aged >= 18 and <= 70.
3. Diabetic foot ulcers classified by Wagner as grade 1 (covering an area >10 and =50 cm2) or grade 2 (covering and 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 be over 0.7. Ulcer = 4 week evolution.
5. Reproductive age men and women should use effective contraceptive methods up to three months after completing treatment.
6. Patients giving informed consent.
---------- Exclusión criteria:
1. Infection signs or symptoms.
Osteomyelitis or ulcers with bone exposure.
2. Poorly controlled diabetes mellitus (Hb A1c > 10%). Morbid obesity (body mass index > 40).
3. Connective tissue disease.
Use of drugs likely to interfere with (corticoids or inmunosuppressors) or to favor cicatrisation (pentoxifylline, prostaglandin, and other growth factors).
4. Uncontrolled systemic or serious diseases: cardiopathies (especially ischemic cardiopathy or heart failure with edema), moderate or serious liver failure, kidney failure with serum creatinine values >200mmol/l.
5. Clinical malnutrition signs or albumin levels < 35 g/L. Hemoglobin < 100g/L.
6. Hypersensitivity to the product or any of its components.
7. History of current or past neoplasia.
8. Failure to conduct relevant evaluations or keep appropriate drainage in affected limb.
9. Previous EGF treatment.
10. Psychiatric or neurological diseases preventing informed consent.
11. History of alcoholism or drug addiction one year prior to inclusion.
12. 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:
3. Phase I
---------- Target Sample Size:
16
---------- First Name (Contact for Public Queries):
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).
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Havana City
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Cuba
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blas.yamir@cigb.edu.cu
---------- Primary Register:
RPCEC
---------- Unique ID number:
RPCEC00000047
---------- Date of Registration in Primary Register:
24/12/2010 18:00
---------- Record Verification Date:
27/04/2009 20:00
Next Update Date:
24/10/2009 19:00
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