Applying a recombinant human epidermal growth factor in the treatment of diabetic foot

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NATURAL HISTORY OF THE DIABETIC FOOT ULCER (DFU)

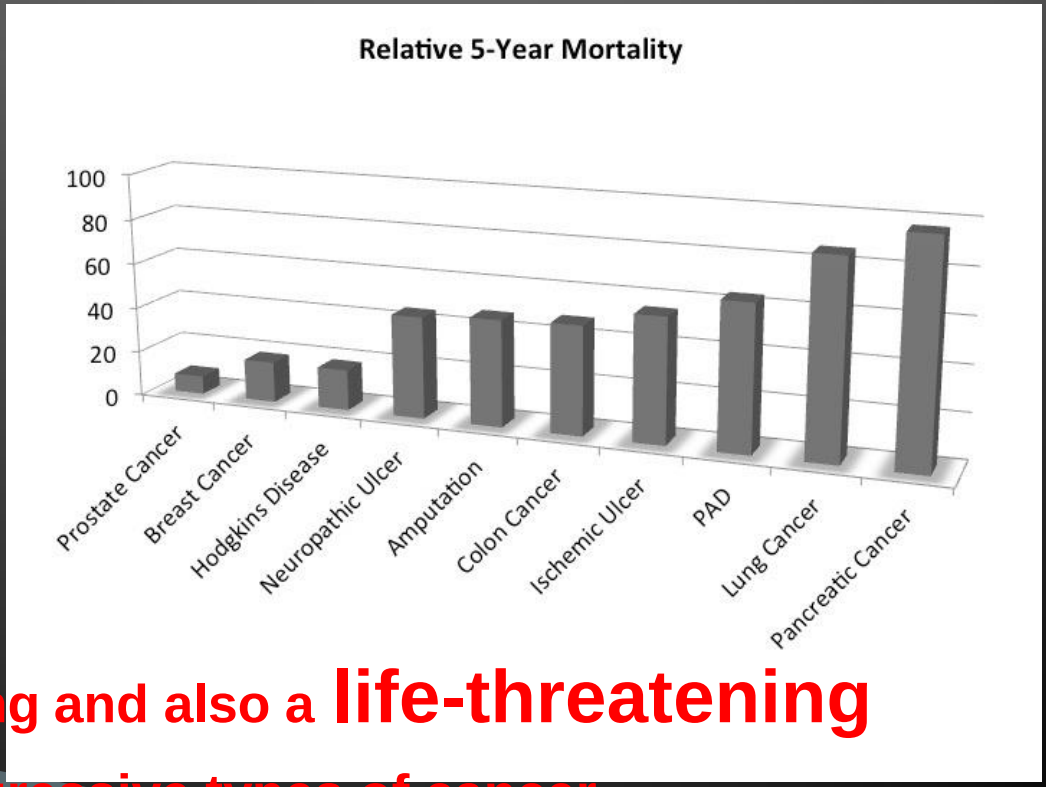
15% of diabetic patients will be affected by DFU

30% of DFU patients never heal the ulcer with standard therapy

15% of DFU patients will end-up in amputation as consequence of the DFU

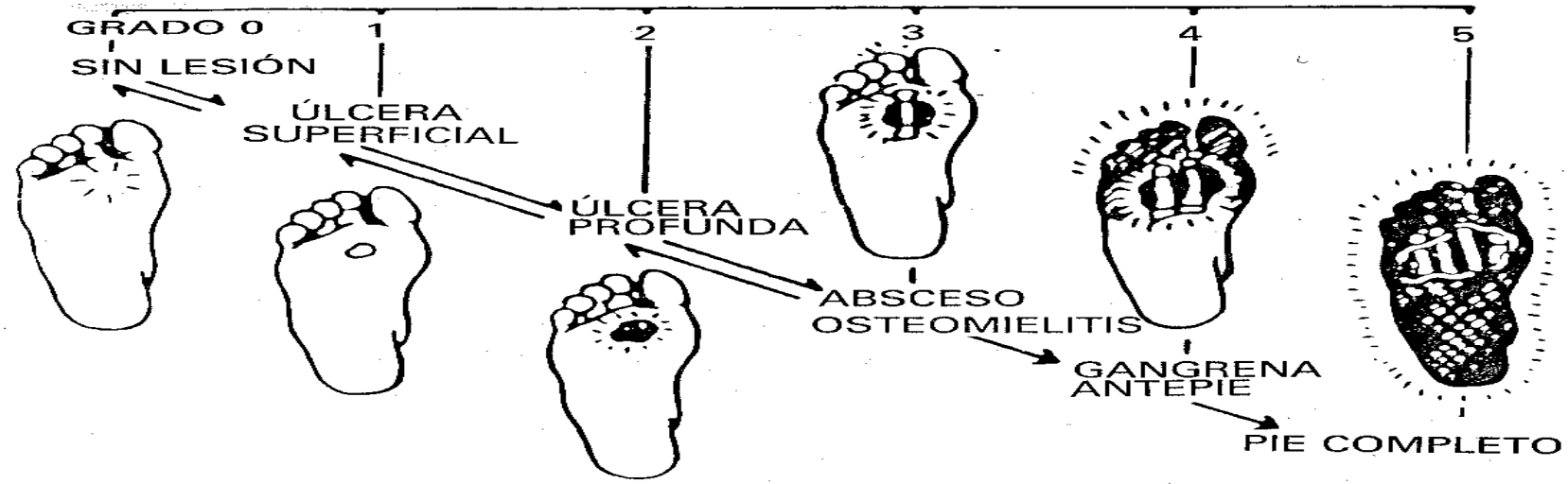
50% of amputees die in a 5-year period, one of the most severe conditions

***Armstrong DG**, Wrobel J, Robbins JM: Are diabetes-related wounds and amputations worse than cancer? Int Wound J 2007, 4(4):286-287.*



Severe DFU is a limb-threatening and also a life-threatening condition, among the most aggressive types of cancer

GRADACIÓN DE WAGNER



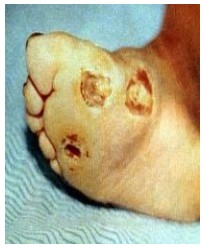
Grado 0

Grado 1

Grado 2

Grado 3

Grado 4



Grado 5

Wagner FW: Supplement. Algorithms of foot care. In The Diabetic Foot. 3 rd ed. Levin ME, O'Neal LW, Eds. St. Louis, MO, CV. Mosby, 19[illegible] 291-302

THE WOUND BED

- It is not a static concept.
- It is neccesary to elimínate obstacles to healing and stimulate the healing process
- There are four components to prepare wound bed

- A) Treatment of diabetes and comorbidities.
- B) Ischemia
- C) Infection
- D)Plantar pressure (offloading)

- Falanga V.(2004) Wound bed preparation:science applied to practice.European wound management association Position Document.London

BACTERIAL BIOFILMS

Chronic and acute wounds are susceptible to the infectious disease, due to innate dermal barrier.

The bacterial biofilm is implied in the infection of all the wounds

The bacterial biofim support protection activity and create inmunological supression.

You can use an array of antimicrobial agents, but the bacterial biofilm help to create resistance to these agents.

That is the reason for introduce the therapies with antibiofilm tool box trying to prevent or eliminate microorganism in the biofilm.

Percival.SL; Hili KE; Williams DW; Hooper SJ; A review of scientific evidence of biofilms in wopunds. Wound Repair Regener. 2012, Sept-Oct, 20(5): 647-57.

DEBRIDEMENT METHODS

- A) Surgical
- B) Sharp
- C) Enzymatic (Papain, Colagenase)
- D) Chemical (Dextranomers,Hydrogen Peroxide)
- E) Autolithyc (Hidrocoloids)
- Mechanical (Wet-to dry)
- Biological (Maggot Therapy)

- Anderson I 2006- Debridement methods in wound care. Nurs Stand.20 (24) PP 65-70.

CURRENT TREATMENT

- Antimicrobial therapy.
- Metabolic control.
- Vascular diagnostic.
- Revascularization.
- Debridement of necrotic tissue or lower amputation if it is required.

Castro G y col. Guía clínica basada en evidencia para el manejo del pie diabético. Med Int Mex 2009;25(6):481-526.

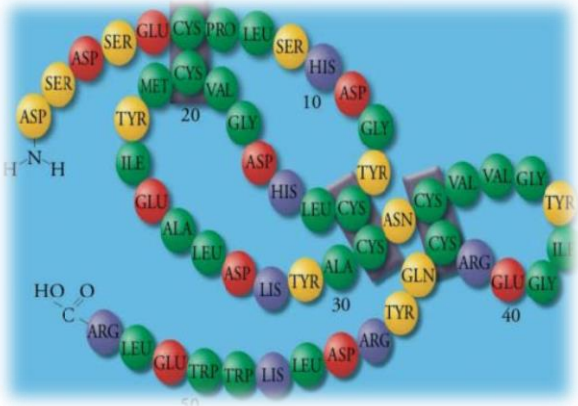
EVENTS INCLUDED IN TISSUE REPAIR OF SKIN STIMULATED BY EGF

BIOLOGICAL EVENT	EFFECTOR CELLS	BRIEF DESCCRIPTION
Chemotaxis	Fibroblasts	Receptors of growth factor are activated after injury, forcinged to migrate
Cell Proliferation	Fibroblasts, endothelial cells keratinocitis	Fibroblasts, myofibroblasts and keratinocytes is divided by EGFR. Fibroplasia contributes to neovascularization and re-epithelialization.
ExtracelularMatrix	Fibroblasts y miofibroblasts	EGF stimulates collagen and gene expression in fibroblast fibrorectina activated. Myofibroblasts cause secretion of the matrix protein and accumulation. Granulation tissue appears .
Angiogenesis	Endothelial cells	EGF stimulates EGFR through transactivation of other receptors
Contraction	Miofibroblasts	EGF enhances the transdifferentiation of fibroblasts to myofibroblasts
Epithelialization	Keratinocytes	EGF stimulates re-epithelialization in the wound by stimulating the migration of the leading edge cells

Epidermal Growth Factor Background

Stanley Cohen

Rita Levi-Moltanci



Molécula de EGF
Polipéptido de 53 AA

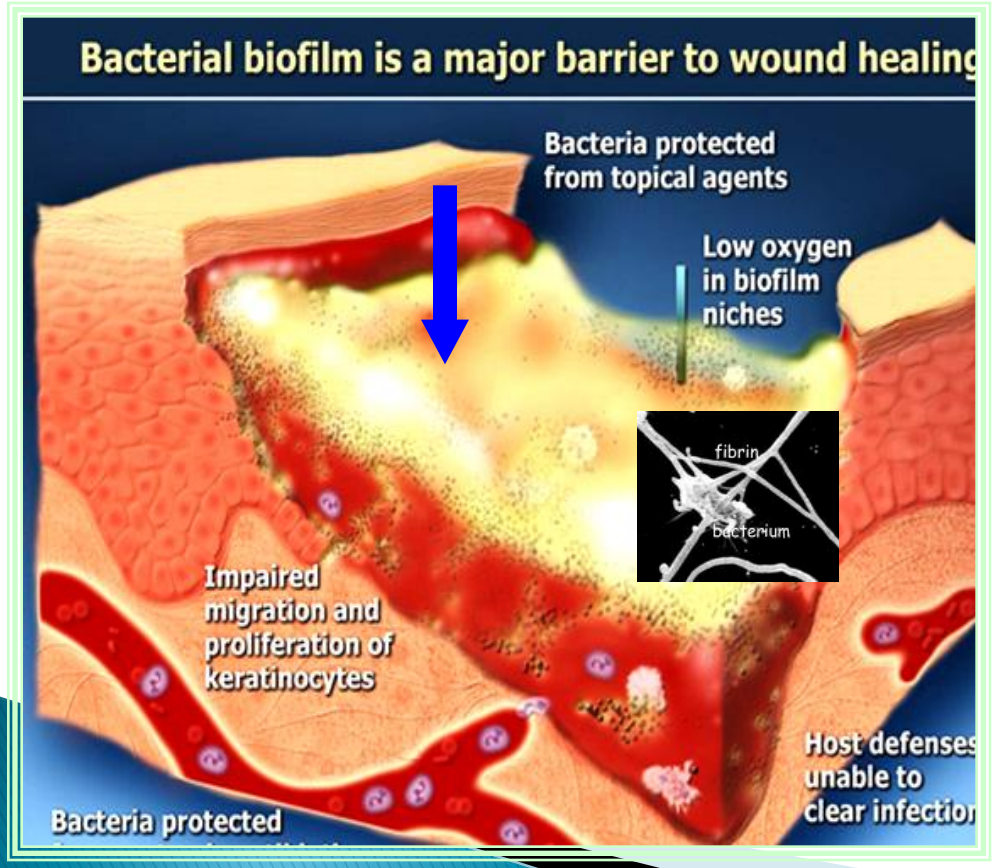
- 1960: Discovered from a semi-pure extract of salivary glands of mice.
- Year 1962: It is demonstrated the effect healing in corneas of rabbits.
- Year 1975: First administration of EGF intravenously.
- 80's. It is demonstrated the stimulating effect of skin healing.
- Year 1989: First U.S. clinical trial. FCE obtained by recombinant.
- 1989: CIGB produced Facdermin (Hebermin).
- 1992: intravenous administration of EGF.
- 2001: Infiltration of EGF in ulcer edges and bottom terminals.
- 2006: Heberprot-P is registered on Cuba

Centro de Ingeniería Genética y Biotecnología

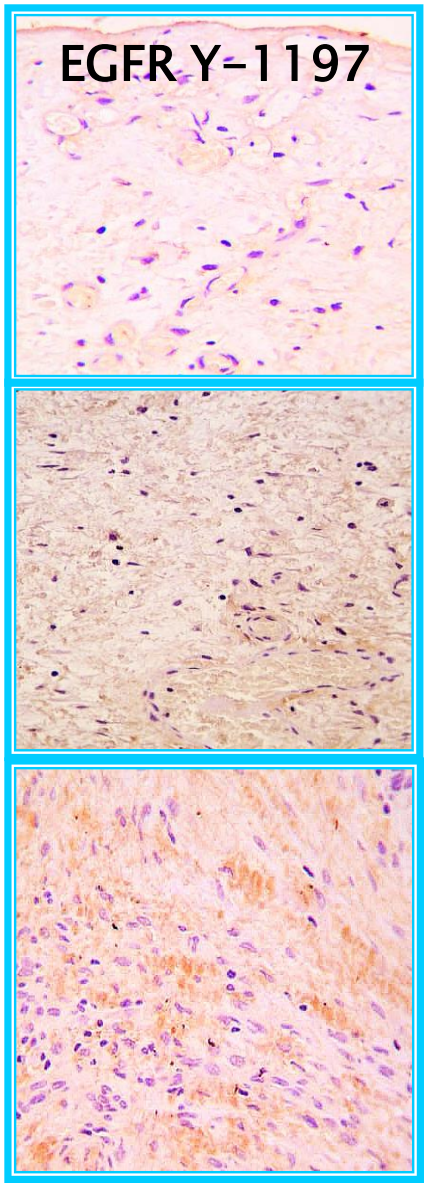
Polo Científico de La Habana

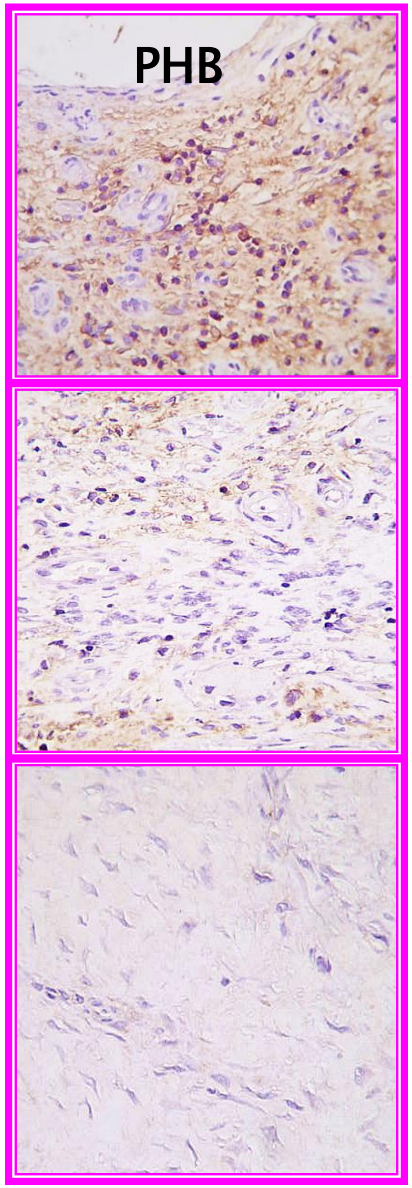
Principales Productos del CIGB

- Vacuna Pentavalente
- Heberprot P
- Vacuna Rec. Hepatitis B
- Vacuna Conjugated Hib
- IFN Alpha-2b Rec.
- IFN gamma Rec.
- GCSF Rec.
- Estreptokinasa Rec.
- EGF Rec.
- Factor de Transferencia
- Kits de Diagnóstico
- Eritropoietina Rec.
- Bionematicida



Estratos de expresión en el TG





CHARACTERISTICS OF THE PHASE I CLINICAL TRIAL IN 29 PATIENTS

1. Exploratory, non-controlled trial in 29 patients.
2. DFU Wagner 3 & 4 patients.
3. Dose of 25 µg three times/week.
4. 86% of granulation response was attained.
5. 59% of total response in terms of limb salvage from amputation was obtained.
6. TGF-β main effector mediating EGF-stimulated granulation process and formation of blood vessels (angiogenesis).

OCTOBER 2005. PHASE II CLINICAL TRIAL. DOUBLE BLIND, DOSE CONTROLLED, FIVE HOSPITALS, 41 PATIENTS

Intralesional injections of Citoprot-P® (recombinant human epidermal growth factor) in advanced diabetic foot ulcers with risk of amputation

José I Fernández-Montequín, Ena Infante-Cristiá, Carmen Valenzuela-Silva, Neobalis Franco-Pérez, William Savigne-Gutierrez, Heriberto Artaza-Sanz, Lourdes Morejón-Vega, Cecilio González-Benavides, Osvaldo Eliseo-Musenden, Elizeth García-Iglesias, Jorge Berlanga-Acosta, Ricardo Silva-Rodríguez, Blas Y Betancourt, Pedro A López-Saura, for the Cuban Citoprot-P Study Group*

Fernández-Montequín JI, Infante-Cristiá E, Valenzuela-Silva C, Franco-Pérez N, Savigne-Gutiérrez W, Artaza-Sanz H, Morejón-Vega L, González-Benavides C, Eliseo-Musenden O, García-Iglesias E, Berlanga-Acosta J, Silva-Rodríguez R, Betancourt BY, López-Saura PA, for the Cuban Citoprot-P Study Group. Intralesional injections of Citoprot-P® (recombinant human epidermal growth factor) in advanced diabetic foot ulcers with risk of amputation. Int Wound J 2007;4:333–343.

ABSTRACT

To investigate the efficacy and safety of recombinant human epidermal growth factor (rhEGF) in advanced diabetic foot ulcers (DFU) A double-blind trial was carried out to test two rhEGF dose levels in type 1 or 2 diabetes patients with Wagner's grade 3 or 4 ulcers, with high risk of amputation. Subjects were randomised to receive 75 (group I) or 25 μg (group II) rhEGF through intralesional injections, three times per week for 5–8 weeks together with standardised good wound care. Endpoints were granulation tissue formation, complete healing and need of amputation. Safety was assessed by clinical adverse events (AEs) and laboratory evaluations.

Authors: J. Fernández-Montequín, MD, Service of Diabetic Microangiopathy, National Institute for Angiology and Vascular Surgery, Havana, Cuba; E Infante-Cristiá, MD, Centre for Biological Research, Clinical Trials Division, Havana, Cuba; C Valenzuela-Silva, MSc, Centre for Biological Research, Clinical Trials Division, Havana, Cuba; N Franco-Pérez, MD, Service of Diabetic Microangiopathy, National Institute for Angiology and Vascular Surgery, Havana, Cuba; W Savigne-Gutierrez, MD, Service of Diabetic Microangiopathy, National Institute for Angiology and Vascular Surgery, Havana, Cuba; H Artaza-Sanz, MD, Angiology Department, 'Enrique Cabrera' Hospital, Havana, Cuba; L Morejón-Vega, MD, Angiology Department, 'Joaquín Albarrán' Hospital, Havana, Cuba; C González-Benavides, MD, Angiology Department, 'Arnaldo Milián Castro' Hospital, Santa Clara, Cuba; O Eliseo-Musenden, MD, Angiology Department, 'Hermanos Ameijeiras' University Hospital, Havana, Cuba; E García-Iglesias, BSc, Clinical Trials Division, Centre for Biological Research, Havana, Cuba; J Berlanga-Acosta, PhD, Division of Pharmaceuticals, Centre for Genetic Engineering and Biotechnology, Havana, Cuba; R Silva-Rodríguez, MSc, Division of Pharmaceuticals, Centre for Genetic Engineering and Biotechnology, Havana, Cuba; BY Betancourt, MD, Clinical Trials Division, Centre for Biological Research, Havana, Cuba; PA López-Saura, MD, PhD, Clinical Trials Division, Centre for Biological Research, Havana, Cuba
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E-mail: lopez.saura@cigb.edu.cu
* Members of Cuban Citoprot-P Study Group are listed in the Appendix.






CHARACTERISTICS OF THE PHASE II CLINICAL TRIAL IN 41 PATIENTS

1. Double blind, dose controlled, randomized and multicenter (5 hospitals), 41 patients.

2. DFU Wagner 3 & 4 patients.

3. Doses of 25 and 75 µg three times/week (to explore the possibility of a dose-dependent response).

4. ≥80% of granulation response was attained in the treatment period (up to 8 weeks).

5. 54% of complete healing was obtained in the follow-up (1 year).

6. 66% of total response in terms of limb salvage from amputation was obtained in the follow-up (1 year).

7. Wound contraction observed in some patients, a property usually abolished in diabetics.

WHAT IS HEBERPROT-P?

- ✓ The CIGB developed a high innovative product, "*first in class*", based on a lyophilized injectable formulation containing human recombinant (hrecEGF) for the treatment of diabetic foot ulcer (DFU), either neuropathic or ischemic, in particular to the most critical stages (Wagner's classification grade 3, 4 & 5), in which there is no other therapeutic solution, but amputation.
- ✓ Heberprot-P is then addressed to **"*<u>An unmet medical need</u>*".**

Long term costs for DFU in diabetic patients in a multidisciplinary setting.

- The purpose of this study was to analyze long-term costs for DFU.
- A retrospective economic analysis was performed of costs for 274 patients during 3 years from healing of an initial foot ulcer, with or without amputation.
- Costs were estimated for inpatient care, outpatient care, home care, and social service.
- The value costs for patients during 3 years of observation was:

- Primary healed patients with critical ischemia, US 26,700
- Primary healed patients without critical ischemia, US 16,100.
- For patients who healed with a minor amputation, US 43,100
- For patients after a major amputation, US 63,100.

- Long term costs are high, mainly due to the need for increase home care, social service,
- Recurrence ulcers and new amputation.

Apelqvist.J; Ragnarson-Tennvall,G,Larsson J; Parsson U.Dept. Int. Med, Lund, Sweden.
Foot Ankle Int. 1995 Jul 16(7) 388-94

New reports says Diabetes Care in USA…….
Medscape. Mar 06, 2013

- Diagnosed diabetes cost the United States an estimated 245 billion dollars in 2012(ADA)

- According to the report, aproximately 22.3 millions people, about 7% of the US population were living with diabetes in 2012, an increase of nearly 5 million since 2007

- The total represents a 41% increase for the ADA" S last estímate of US 174 billions in 2007.

- 33% of these costs were linked to the treatments of DFU.

Before Application

- - Glycemic Control with Insulin therapy
- -psychologic preparation
- Handwash
- Product handling
- Wet cure with antiseptic solutions and saline solution
- Use of sterile material (gauze, dressing, bandage)-

- Collective of authors: Infiltration of HEBERPROT -P. An effective treatment for DFU.
- Center for Genetic Engineering and Biotechnology of Havana Cuba,2010
- Elfos Scientiae Publisher,2010,Reprint-2011.

Procedures to apply Heberprot-P

-Equipment and materials.

-Heberprot-P bulb storage at 2-8°C.

-Saline solution 0.9%.

-Disposable syringe 5 ml.

-Disposable needles with different diameters.

-Gloves.

Previous:

-Psychological preparation. Wash hands

-Local cure.

- Heberprot-P bulb dilution

Trans:

- Intralesional product injection at border and bottom of the lesion.

- Insert needle at 0.5 cm deep.

- Apply from 0.5 to 1 ml of product in wound border and bottom.

- Change needles when needed.

-Start applying the product in cleanest wound site.

- Use occlusive bandages.

.

ADMINISTRATION.

- Treatment should be adminístrate 3 times per week.

- USE HEBERPROT P UNTIL:
- A) complete granulation tissue is achieved
- B) the wound is closed with a skin graft.
- C) spontaneous closure.

- The mean number of injections: 10-12.
- With the first 6 application, the granulation tissue will appears.
- Top: 24 injections.

- Collective of authors: Infiltration of HEBERPROT -P. An effective treatment for DFU.
- Center for Genetic Engineering and Biotechnology of Havana,Cuba, 2010
- Elfos Scientiae Publisher,2010
- Reprint, 2011.

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¿ CAN HEBERPROT-P CHANGE HEALING PARADIGMS IN THE DIABETIC FOOT?

Previous surgical treatment for therapy with HEBERPROT P . Paradigms

- – Exposed tendon
- – Exposed bones
- – Bone sequestrations
- – Heel necrosis
- – Wound spreading.

Montequin J.I; Mena G; Santiesteban Ll. Tratamiento y recuperación del PD grado 5(Wagner) utilizando HEBERPROT P. Biotecnología Aplicada 2010;vol. 27, No. 2

Clasificación Etiopatogénica del Profesor Mc Cook

- Pie Diabético Neuroinfeccioso

Mal perforante plantar

BACKGROUND

Foot Amputation may be indicated when the neuropathy, vascular disease or ulcerative deformity has led to tissue necrosis

Amputation and rehabilitation of the diabetic foot
Sage R; Pinzur M; Stuck R; Napolitano C. The Diabetic Foot. 2nd edition

Ulcer with more than 190 cms2

Lesions with bone and tendon exposure in ankle and leg

BACKGROUND

Transmetatarsal amputation is indicated when there is necrosis either in an osteal tissue or a tendon.

Transmetatarsal amputation is indicated when there are several ulcers in the foot or three or more toes are missing.

Mc Kittric L.S. Transmetatarsal amputation for infection or gangrene in patients with D.M. Ann Surg 1949 130: 826 - 831

BACKGROUND

Either toe amputation or Ray resection are indicated when there is irreversible necrosis in a toe without media or lateral extension.

Ulcer deep infection up to the bone level is an appropriate indication that amputation is required.

Gianfortune P; Piella RJ; Ray resection in the insensitive or dysvascular foot. J Foot Surg 1985 – 24:103 – 10

Toe reconstruction in toes with bones lesions

Will you use HEBERPROT P IN THE ISCHEMIA?

Why not?

F.P.

Ischemia and diabetes

Topography .

- Over 50% of occlusive lesions are more than 10 cm.
- 30% had occlusive lesions distal to the 3 trunks.
- 50% have a unique artery to the foot.

Collateral topography.
In ischemic heart disease is reduced by decreasing the collaterals of monocyte migration capability.
By increasing the activity of metalloproteases and angiostalina which are angiogenesis inhibitors.

- Ischemic diabetic foot.
- Index pressure of 0.6 mm Hg.
- Femoro popliteal by pass.
- After six months, the ulcer didnt heal.

The patient received 12 doses of HEBERPROT P

- After 4 months of a femoro posterior tibial artery revascularization, the ulcer didnt heal.
- Index pressure :0.7 mm Hg.
- He received 18 doses of HEBERPROT P

Before treatment

3 weeks


02/08/2010 12:29

- Diabetic Ischemic foot with infectious ulcer.
- Index Pressure 0.6 mm Hg , after a femoro popliteal by pass.
- Leucocytes. 21,000
- The patient refused to be amputated.

What to do with this patient?

Do you use HEBERPROT P?


09/09/2010 10:11


2010/12/14 11:1

¿Will you use HEBERPROT P in a patient without outflow tractus ?

First dose

Most frequents adverse events

- Shiverings
- Chills.
- Pain and burning sensation in the administration site.
- (Tolerated by the patients and manageable by the physician)

In a 49 series review of diabetic foot revascularization they consider it as good results when total healing time is of 60% at 12 months.

A systematic review of the effectiveness of revascularization of the ulcerated foot in patients with diabetes and peripheral arterial disease. Diabetes/metabolism research and reviews supplement: proceedings of the 6th international symposium on the diabetic foot, may 10-14, 2011, noordwijkerhout, the netherlands

19 diabetic patients received conventional surgical revascularization , It was considered as good results a 60% total healing of diabetic foot ulcer at 24 months.

Diabetic critical ischemia of lower limbs: distal arterial revascularization. Acta chir belg. 2009 may-jun;109(3):321-6.

What can happen during this long time period?

With the use of infrapopliteal endovascular revascularization, in the treatment of ischemic diabetic foot, we tried to get direct flow on 121 patients.The rate of healing ulcers was 72% in 12 months;using indirect surgery, they got only 45%.

Sodestrom M;Alback A.Angiosome-targeted infrapopliteal endovascular revascularization for treatment of DFU.J.Vasc.Surg,2012,Dec.6.

Diabetic foot disease: impact of ulcer location on ulcer healing.

The mid time of healing of ulcers in the toe was 147 days (135-159 days)
In ulcers of the forefoot 188 days (158-218 days)
In heel ulcers , 237 (205-269 days)
plantar ulcer 172 days.

Pickwell K.M; Sieasma VD; Kais M; Holstein PE in Diabetes metab. Res, Rev. 2013,Feb.7

HEBERPROT-P. CLINICAL DEVELOPMENT. SUMMARY

Registration (20): Cuba, Algeria, Argentina, Uruguay, D. Republic, Venezuela, Paraguay, Ecuador, Mexico, Libya, Colombia, Guatemala, Georgia, Ukraine, Vietnam, Philippines, Panama, Peru, Costa Rica, Russia.

Patent Granted: United States, European Union, Japan, Canada, Australia, Hong Kong, Singapore, South Korea, South Africa, Russia, China, India, Indonesia, Malaysia, Ukraine, Mexico, Argentina and Cuba. Filed: Brazil, Thailand and Chile.

CLINICAL TRIALS

1. Phase I: 45 patients, 16 patients in PK trial
2. Phase II: Cuba, 166 patients (4 trials)
3. Phase III: 149 patients
4. Pharmaco-vigilance in Cuba: 1,788 patients
5. Impact study in Cuba: 2,833 pacientes
6. Clinical trials finished in Russia, Indonesia, Seychelles
7. Clinical trials ongoing or in design in China, European Union, Ukraine, Belarus, etc

NATIONAL APPLICATION

1. National Program in Venezuela: > 116,000
2. National Program in Cuba: > 28,000
3. Argentina (1,000), Ecuador (693), Turkey (599), Algeria (285), Libya (176), Dominican Republic (135) other 17 countries (> 4,000).

Total: > 147,000 patients

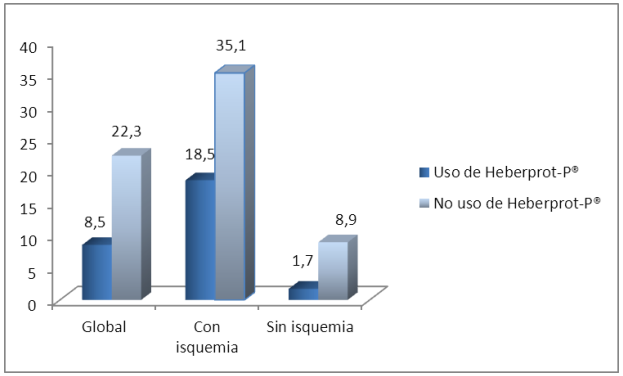
Time 0

5 weeks

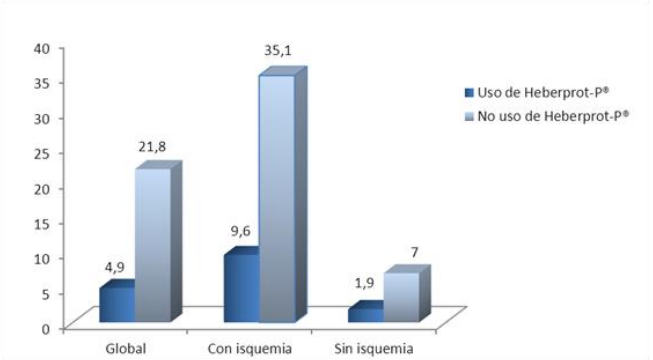
3 months follow up

Impact of use of Heberprot-P

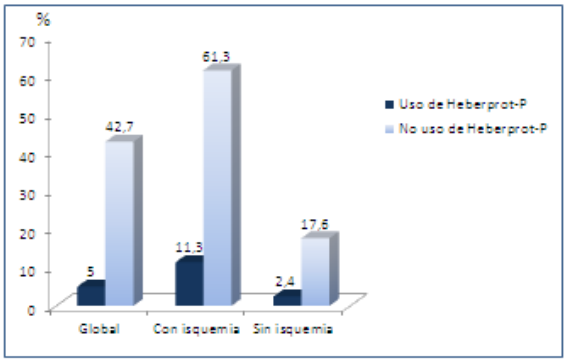
Impact study I



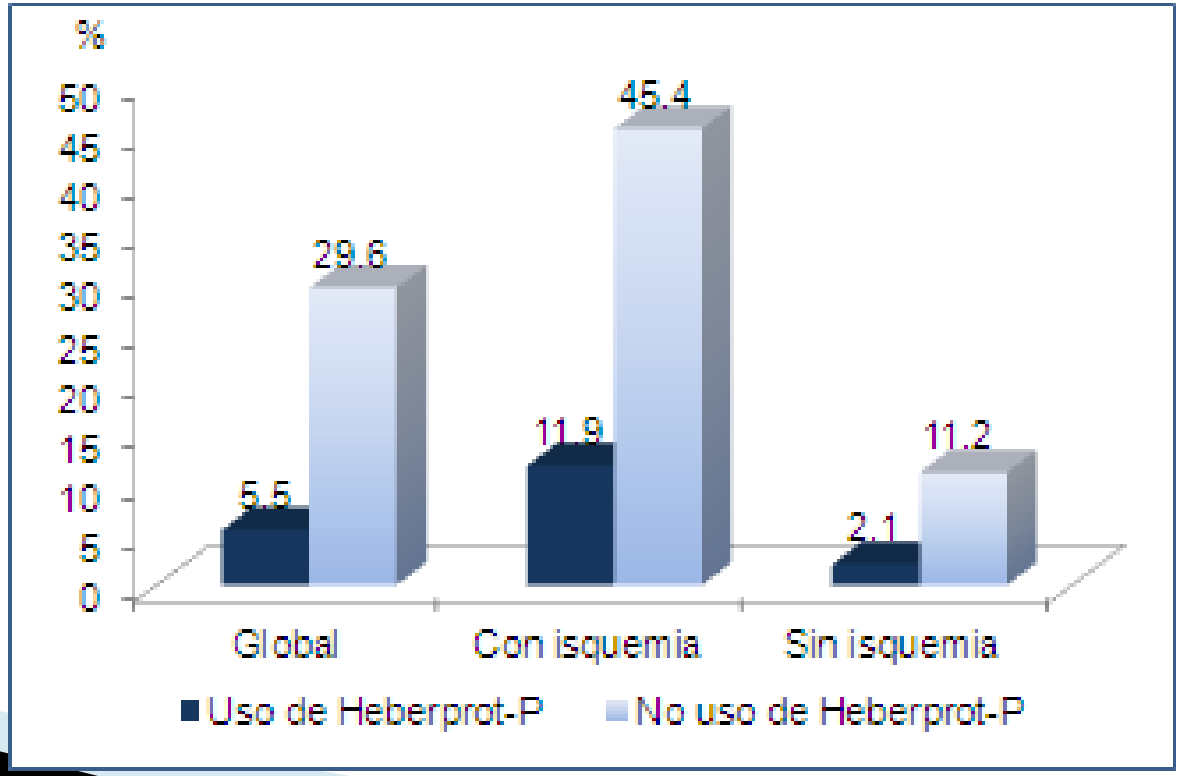
Impact study II



Impact study III



	Use of Heberprot-P®	
	Yes	No
Global	72/1300 (5.5%)	460/1553 (29.6%)
With ischemia	54/455 (11.9%)	378/832 (45.4%)
Without ischemia	18/837 (2.1%)	80/714 (11.2%)
Not classifiable	0/8 (0.0%)	2/7 (28.6%)



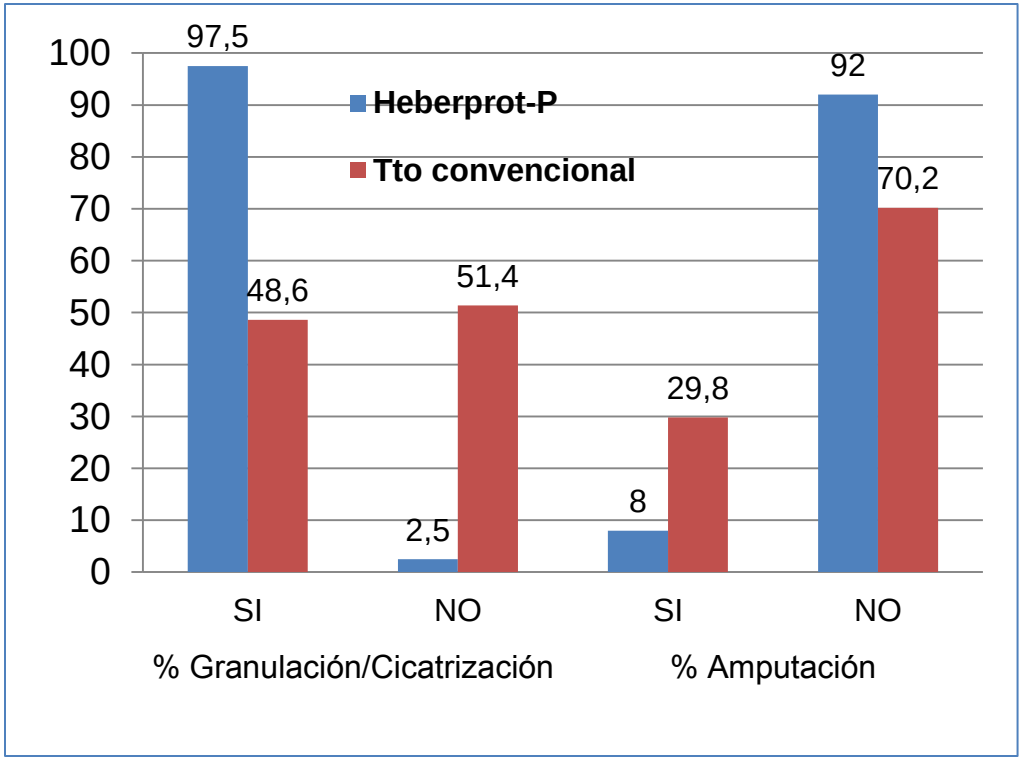
IMPACT OF THE USE OF HEBERPROT-P IN DFU PATIENTS WITH RESPECT TO AMPUTATIONS IN ARGENTINA (2012)

- Retrospective study: Buenos Aires City (2), Buenos Aires Province (1), Santa Fe (2) and Cordoba (1).

- 268 patients, distributed in two groups:

Study Group (Treatment with Heberprot-P) = **163**

Control Group (Standard care) = **105**



PROPERTIES AND ADVANTAGES OF HEBERPROT-P

1. Stimulate the granulation and accelerate re-epithelization in diabetic foot ulcer and ischemic, atonics, hard-to-heal diabetic lesions.
2. Reduce the time for healing.
3. Reduce the number and extension of surgical debridements and local recidivisms.
4. Attenuates reperfusion damages.
5. Offers potential contribution to limb salvage.

EFFECTIVE SOLUTION TO AN UNMET MEDICAL NEED

Strong Pipeline Candidates Will Encourage Competition in DFU Therapeutics Market

GlobalData found that the product pipeline for DFU is strong, with 35 molecules in various stages of clinical development. There are eight molecules in Phase III, 19 in Phase II and six molecules undergoing Phase I clinical trials. The entry of Pexiganan (pexiganan acetate) for the treatment of mild infections and Fragmin (dalteparin sodium), trafermin and CVBT-141B for wound healing will impact the market. Heberprot-P and dermagen of late stage are also promising molecules under clinical development. These pipeline products are as safe and efficacious as the current market products with novel formulation or routes of administration. They target the significant unmet need that exists in the market.

DIABETIC FOOT ULCER (DFU) THERAPEUTICS - PIPELINE ASSESSMENT AND MARKET FORECASTS TO 2019 (Cont.)

Figure 38: Technology Trends Analytic Framework of DFU Therapeutics Pipeline, 2010

	Preclinical	Phase I	Phase II	Phase III
First-in-class (28)	• Chrysalin(TP 508) • GLYC- 101	• Galnobax • Iroxanadine • Telbermin • FGF-1	• CVBT-141B • DCB-WH1 • DSC127 • HO/03/03 • Nexagon • Sonedenoson(MR E0094) • Talactoferrin	• Fragmin • Pexiganan(MSI-78) • Trafermin • Daptomycin • Dermagen • Heberprot-P
Me-too (5)			• Biochaperone PDGF-BB • Excellarate • KUR-211 • NanoDOX	• Cogenzia
Product-Extension (2)			• Gentamicin-collagen sponge + Levofloxacin • Isoniazide	
	2	6	19	8

Source: GlobalData, Pharma eTrack from GlobalData, ClinicalTrials.gov, Company Websites

HEBERPROT-P SUMMARY

1. Indicated for the treatment of recalcitrant, large-size diabetic ulcers, reluctant to current comprehensive conventional interventions.
2. Registered in Cuba since June 2006 and included within the National Medical Formulary since April 2007.
3. Authorized in Cuba, Algeria, Argentina, Uruguay, D. Republic, Venezuela, Paraguay, Ecuador, Mexico, Libya, Colombia, Guatemala, Georgia, Ukraine, Vietnam, Philippines, Panama, Peru, Costa Rica, Russia.
4. Patents Granted: United States, European Union, Canada, Australia, Hong Kong, Singapore, South Korea, South Africa, Russia, China, India, Indonesia, Malaysia, Ukraine, Mexico, Argentina, Japan and Cuba.
5. Filed: Brazil, Thailand and Chile.
6. Gold medal by the WIPO (March, 2011) and Prize to the best young inventor in the 39 International Fair Geneva, Switzerland (April, 2011).

Inventions Geneva

THE WORLD'S LARGEST MARKET-PLACE FOR INVENTIONS

WIPO
WORLD INTELLECTUAL PROPERTY ORGANIZATION

WIPO AWARD FOR BEST YOUNG INVENTOR

JORGE BERLANGA ACOSTA

is hereby awarded
the WIPO AWARD FOR BEST YOUNG INVENTOR

for the invention:
HEBERPROT-P (USE OF A PHARMACEUTICAL COMPOSITION CONTAINING EGF FOR DIABETIC FOOT AMPUTATION PREVENTION

presented at the
WIPO "Universities' Pavilion"
39th International Exhibition of Inventions of Geneva

organized by the
World Intellectual Property Organization (WIPO)

Geneva
April 6 – 10, 2011

Francis Gurry
Director General
WIPO

Premio Mejor Inventor Joven de la Feria Internacional de Invenciones Ginebra 2011

OMPI
ORGANIZACIÓN MUNDIAL DE LA PROPIEDAD INTELECTUAL

PREMIO DE LA OMPI PARA EL MEJOR INVENTOR

CENTRO DE INGENIERÍA GENÉTICA Y BIOTECNOLOGÍA

(JORGE BERLANGA ACOSTA, JOSÉ I. FERNÁNDEZ MONTEQUÍN, CALIXTO VALDES PÉREZ, NEOBALIS FRANCO PÉREZ, INGRID ROJAS CONSTANTÍN, HÉCTOR SANTANA MILIÁN, LARISSA CHACÓN CORVEA, GERARDO E. GUILLÉN NIETO, LUIS HERRERA MARTÍNEZ, LEONARDO CANAN-HADEN FRÍAS, HAYDEE GERÓNIMO PÉREZ Y JORGE PEÑA SOTOLONGO)

Se otorga el premio de la OMPI para el Mejor Inventor en reconocimiento a la invención "Uso de una composición farmacéutica que contiene factor de crecimiento epidérmico (EGF) para la prevención de la amputación del pie diabético"

La Habana
22 de marzo de 2011

WIPO | OMPI
WORLD INTELLECTUAL PROPERTY ORGANIZATION
ORGANISATION MONDIALE DE LA PROPRIÉTÉ INTELLECTUELLE

Francis Gurry
Director General
OMPI

Premio Medalla de Oro de la OMPI a la Mejor Invención

Marzo 2011

DIABETES AND DIABETIC FOOT ULCER OUTLOOK IN TURKEY

- Turkish population (20-79 years): 48,294,000[1]
- Diabetes prevalence (14.58%) :7,043,290[2]
- DFU incidence / year average (3.5%) : 246,515[3,4,5]
- DFU (most severe grades of Wagner 3, 4 and 5) (~60%): 147,909[6]
- Around 30% of those patients are amputated (**~44,372**)[7,8]

REFERENCES

1,2 IDF World Atlas 2012.

3 Diabetes Care 1999: 22, 382-387.

4 Diabetes Care 2002: 25, 570-574.

5 Diabetes Med 2002: 20, 377-84.

6 ISPOR 12th Annual European Congress, Paris, France. October, 2009.Cost of an episode of diabetic foot ulcer in Spain.

7 Annual incidence of LEA. Epidemiology of the diabetic foot: Ulcerations and amputations. Advances in Wound Care. April 1999 (Frykberg, Roberts G).

8 DiabetesVoice, November 2005/Vol. 50/ Special Issue.

Can HEBERPROT P change your healing paradigms in the treatment of diabetic foot?

Del 8 de diciembre del 2014 al 12 de diciembre de 2014

Curso Taller Internacional

(Del 8 al 9 de diciembre de 2014). Sede: Hotel Mellá Habana, Cuba.

Precongreso sobre la Aplicación Práctica del Factor de Crecimiento Epidérmico humano recombinante (FCEhr) en Pacientes con Úlceras de Pie Diabético

Congreso Internacional

(Del 10 al 12 de diciembre de 2014.) Sede: Centro de Convenciones Varadero, Varadero, Cuba.

Controlando a la diabetes y a sus complicaciones más severas.

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Thank you very much
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