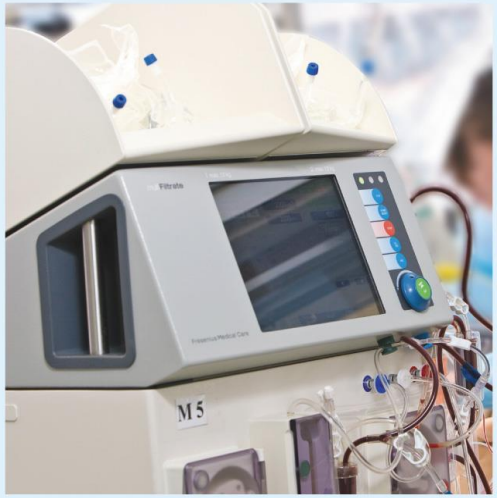
FAKULTNÍ NEMOCNICE OSTRAVA

Clinical Translational Research in Regenerative Medicine

Critical Limb Ischemia



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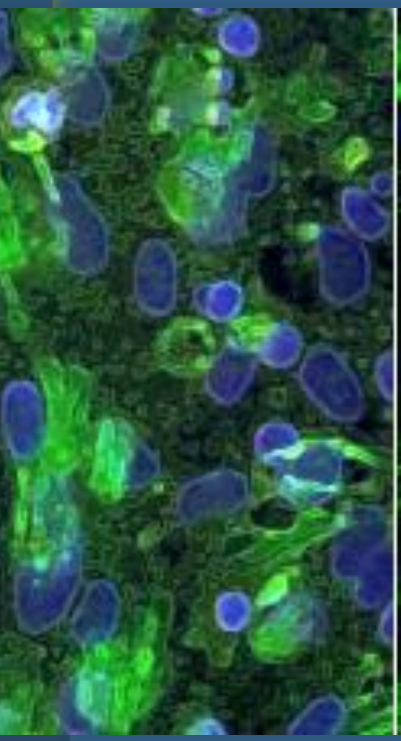
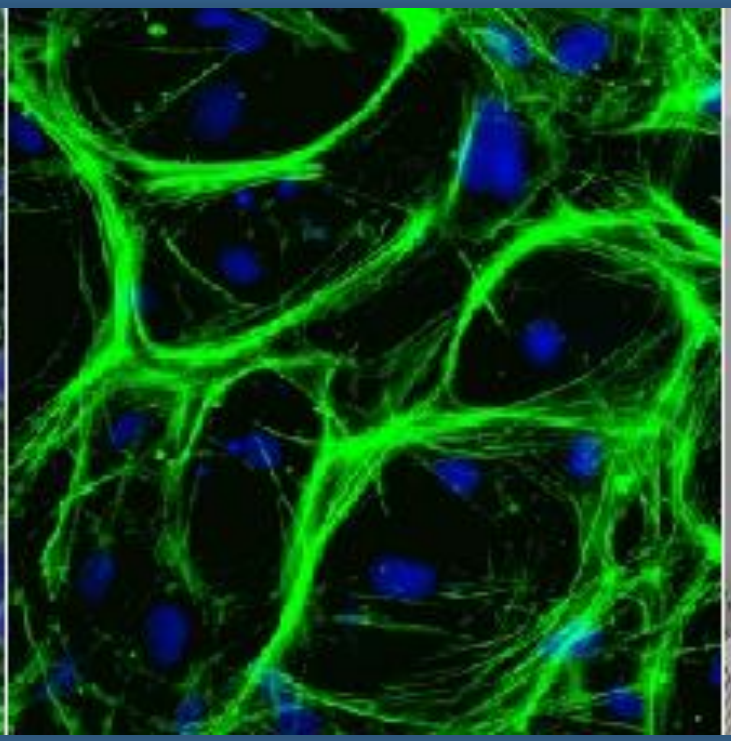
RIS Regionální inovační strategie Moravskoslezského kraje





Moravian Silesian - Biotechnology Cluster

FAKULTNÍ NEMOCNICE OSTRAVA

Václav Procházka,MD,PhD.,MSc

R&D in FN Ostrava

Occupation or position held:

Chief Interventional Neuroradiology and Angiology Department

Vice director for R&D UH-Ostrava

Main activities:

Neurovascular Interventions

Stroke Research

Diagnostic and Interventional Radiology

Diagnostic and Therapeutic Angiology

Peripheral Vascular Disease Research

Adult Stem Cell Research

Brain Tumors research

Deep Burn trauma research

MS Biotechnology Cluster Research

Stem cell reserach

- Cryobanking technology
- Critical Limb Ischemia stem cell therapy
- Typ1 DM stem cell therapy research
- Breast Cancer Adipose tissue stem cell therapy
- Orthopedics stem cell research
- COPD stem cell therapy

Nanotechnology biotech research

- Nanobiosensors and Nanoprinting, 3D-Bioprinting technology
- Nanotoxigology and Nanopathology research
- Biodesign SIS Layers for Wound healing collaborative research
- Kidney Transplant Grafts Rejection Prevention
- Nanotechnology and Biosimilars
- New Materials for Traumatology, 3D-Printing

Genetic reserach in Degenerative Brain disease

- Genomics, whole genom analysis,
- Pharmacogenomic studies
- Alzheimer and PD research
- Autistic spectra disorders, genetics and stem cell therapy
- Amyotrophic lateral sclerosis, genetics and conditioned media therapy
- Dementia and degenerative diseases

Environmental biological research

- Environmental influence in Diabetic patients research
- Brain tumors and Enviromental influence
- Stroke and Enviromental influence

Bioinformatics and medical data analysis

- Center of Biocybernetics and Data Analysis
- Biostatistics and Robust Data Analysis
- Medical Imaging Predictive models
- RFID technologies

Regionální inovační strategie Moravskoslezského kraje

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Goal of stem cell therapy
- Regeneration (916)
- Cell therapy (nonregenerative) (126)
- Gene therapy (96)
- Stem cell collection/mobilization (30)
- Bioscaffold (15)
- Immunotherapy (13)

Target of stem cell therapy
- Immune system (260)
- Heart (197)
- Marrow (157)
- CBS (125)
- Vascular system (90)

Mechanism of disease being treated
- Injury or degeneration (400)
- Ischemia (274)
- Drug – (chemotherapy) or radiation-induced damage (224)
- Immune attack (142)
- Congential or inherited disease (79)
- Neoplasia (52)
- Infection (10)
- Healthy volunteers (10)

Principle disease/condition targeted
- Cardiovascular disease (278)
- Neurological disease (169)
- Cancer (97)
- Liver disease (67)
- Bone condition (65)
- Other (56)
- Immunodeficiency and other nonmalignant hematologic condtitions (49)
- Gastrointestinal disease (46)
- Systemic rheumological disease (45)
- Diabetes (43)
- Eye disease (39)
- Skin condition (19)
- Organ transplant-associated (18)
- Lung disease (15)
- Kidney condition (8)

Stem cell type
- Hematopoietic (432)
- Mesenchymal (432)
- Endothelial progenitor cells (69)
- Other (69)
- Neural (22)
- Unspecified (20)
- Limbal (16)
- Embryonic (6)
- Cardial (6)

Stem cell tissue source
- Bone marrow (439)
- Peripheral blood (170)
- No sampling (112)
- Umblical cord (99)
- Unspecified (95)
- Adipose tissue (92)
- Eye (16)
- Brain (12)
- Placenta (9)
- Heart (6)
- Embryo (6)

Stem cell manipulation
- Cultured (441)
- Purified (236)
- Drug treatment (95)
- Gene modified (79)
- None (115)
- Other (49)
- Unspecified (43)

Graft donor source
- Autologous (594)
- Allogeneic (305)
- Autologous and allogeneic
- No stem cell graft (118)
- Nospecified (33)

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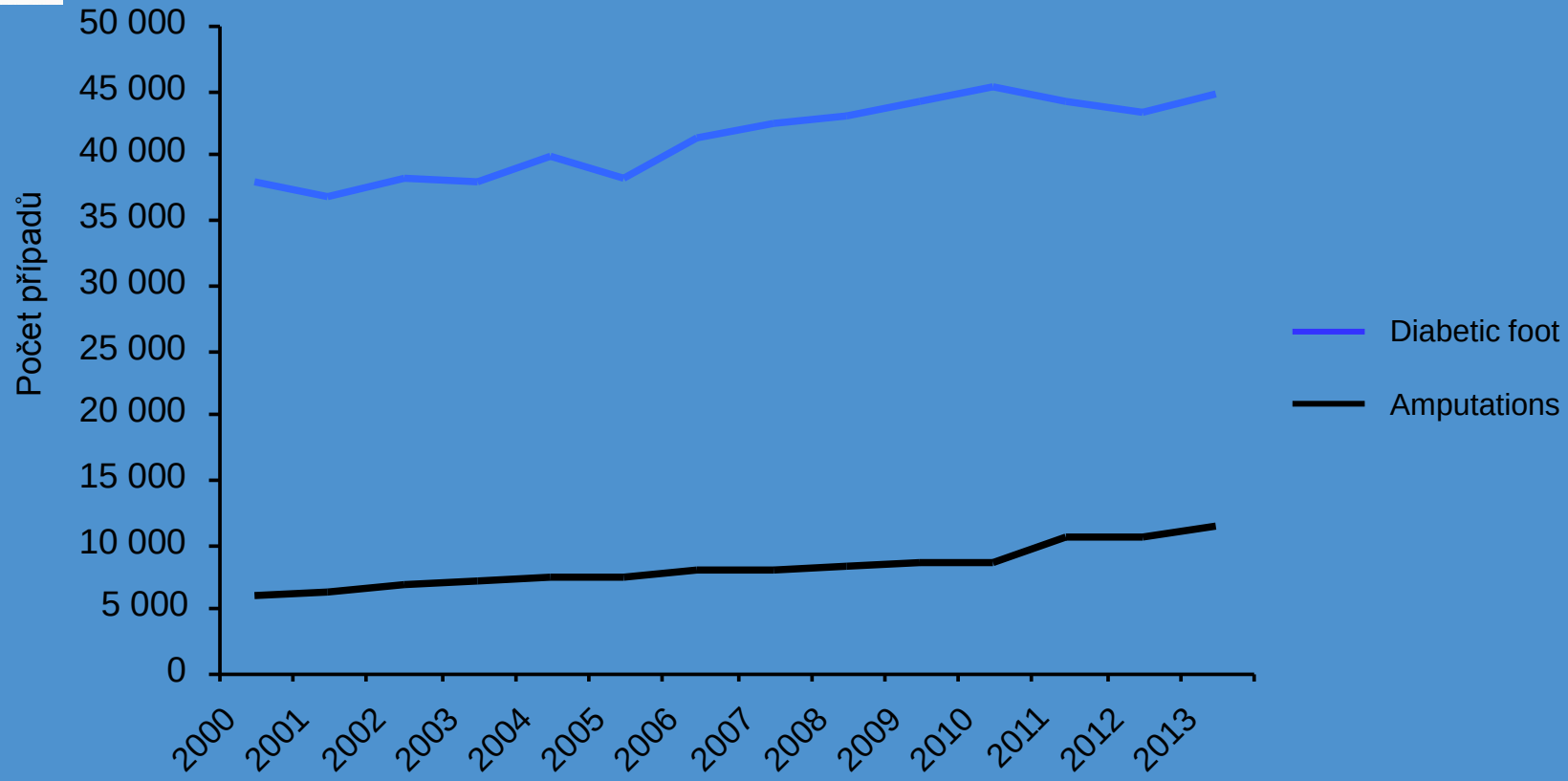
RIS RIS RIS Regionální inovační strategie Moravskoslezského kraje

Diabetic foot and amputation rates in Czech republic



	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Diabetická noha	37 764	36 725	38 166	37 971	39 753	38 090	41 328	42 337	42 992	43 990	45 118	44 011	43 248	44 657
Amputace (%)	5 865 (15,53 %)	6 118 (16,66 %)	6 743 (17,67 %)	7 029 (18,51 %)	7 444 (18,73 %)	7 303 (19,17 %)	7 834 (18,96 %)	7 853 (18,55 %)	8 169 (19,00 %)	8 439 (19,18 %)	8 501 (18,84 %)	10 408 (23,65 %)	10 425 (24,11 %)	11 168 (25,01 %)

Zdroj: Výkazy o činnosti zdravotnických zařízení pro obor diabetologie (A04), období: 2000 - 2013

Diabetic foot and amputation prices in FNO

Souhrn vykázané/uznané péče za pacienty, kteří prodělali amputaci kvůli poruše oběhového systému, kromě horních končetin a prstů u nohy, viz DRG báze 0515

(data za 01/2011 – 10/2014 (hosp. data dle DRG; preskripce a poukazy na zdrav. prostředky; amb. produkce)
zdroj dat: Archív vykázané/uznané péče FNO (datový sklad OSVZP a ODFA)

	HOSPITALIZACE dle DRG							PRESKRIPCE HVLP, IVLP a ZP na poukaz					AMBULANCE**			
ROK	počet RČ dle DRG báze 0515	body	LP	Zum, Zulp	HOSP. ve výkonově HB 0,90 Kč	CM	Úhrada HOSP. (vše přes Případový paušál DRG (před i po amputaci)	počet RČ dle DRG báze 0515 (před i po amputaci)	HVLP	IVLP	ZP	Preskripce Léků a ZP na pac. (před i po amputaci)	počet RČ dle DRG báze 0515 (před i po amputaci)	body	Zum,Zulp	Úhrada AMB. (před i po amputaci)
2011	67	6 694 648	173 570 Kč	1 291 037 Kč	7 489 790 Kč	247,4431	7 588 940 Kč	76	708 940 Kč	0 Kč	446 666 Kč	1 155 606 Kč	97	2 550 391	481 640 Kč	2 536 251 Kč
2012	61	6 277 889	165 970 Kč	1 543 014 Kč	7 359 084 Kč	228,9441	7 727 830 Kč	76	833 484 Kč	0 Kč	507 724 Kč	1 341 208 Kč	88	2 791 178	420 305 Kč	2 648 300 Kč
2013	70	7 075 759	198 465 Kč	1 870 630 Kč	8 437 278 Kč	273,6646	8 706 160 Kč	68	526 295 Kč	0 Kč	337 734 Kč	864 029 Kč	94	2 400 561	685 029 Kč	2 571 565 Kč
01-10/2014	52	5 443 352	129 240 Kč	1 351 064 Kč	6 379 320 Kč	185,3878	6 106 743 Kč	55	445 878 Kč	0 Kč	267 377 Kč	713 254 Kč	73	694 910	118 054 Kč	686 750 Kč
Celkem		25 491 648	667 245 Kč	6 055 744 Kč	29 665 472 Kč	935,4396	30 529 673 Kč		2 514 597 Kč	0 Kč	1 559 501 Kč	4 074 097 Kč		8 437 040	1 705 028 Kč	8 443 366 Kč

*r. 2011-2013 výpočet dle vyúčtování zdrav. služeb bodů jednotlivých ZP ve vše Případovým paušálem (jako Alfa DRG); r. 2014 dle Úhradové vyhlášky ve vše Případovým paušálem (jako Alfa DRG)

**body přepočteny k 1.1.2014; úhrada za body dle HB dle úhradové vyhlášky (HB snižována) včetně výkonů: klinické stomatologie; CyberKnife; SDH; lůžek sociální péče; foniatrických pomůcek

ROK	prům. HOSP.	prům. PRESKR.	prům. AMB.	Vážená prům. úhrada na RČ (Hosp, Preskr., Amb.)
2011	119 238 Kč	15 205 Kč	26 147 Kč	**160 590 Kč**
2012	126 586 Kč	17 647 Kč	30 100 Kč	**174 333 Kč**
2013	124 374 Kč	12 706 Kč	27 357 Kč	**164 437 Kč**
01-10/2014	117 437 Kč	12 968 Kč	9 408 Kč	**139 813 Kč**

Mean = 166 500 CZK
Prosthesis = 85 000 CZK
wheelchair = 40 000 CZK
Celkem= 291 500 CZK

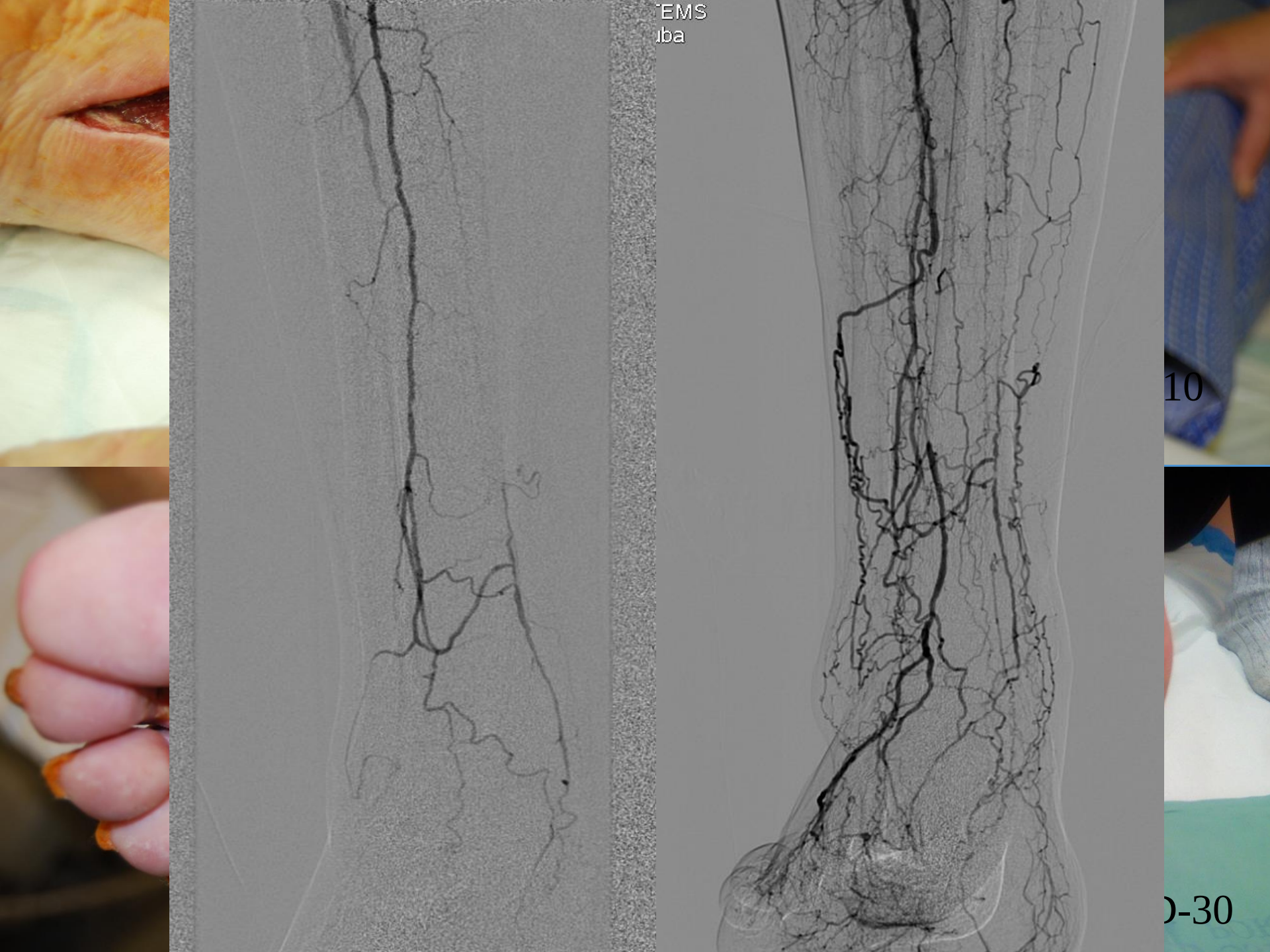
Rehabilitation costs
Social-economic costs
EURODIALE – 500 600 CZK


SmartPrep 2
HARVEST

BEFORE	AFTER
	
	

BEFORE	AFTER
	
	

BEFORE	AFTER
	
	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CELL TRANSPLANTATION
The Regenerative Medicine Journal

Cell Therapy, a New Standard in Management of Chronic Critical Limb Ischemia and Foot Ulcer

Journal:	*Cell Transplantation*
Manuscript ID:	CT-0067
Manuscript Type:	Original Article
Date Submitted by the Author:	15-Feb-2010
Complete List of Authors:	Prochazka, Vaclav; University Hospital Ostrava, Interventional Neuroradiology and Angiology Department Gumulec, Jaromír; University Hospital Ostrava, Hemato-Oncological Center Jalůvka, František; University Hospital Ostrava, Surgery Clinic and Anaesthesiology Department Šalounová, Dana; VŠB-Technical University Ostrava, Department of Mathematical Methods in Economy Jonszta, Tomáš; University Hospital Ostrava, Interventional Neuroradiology and Angiology Department Czerný, Daniel; University Hospital Ostrava, Interventional Neuroradiology and Angiology Department Krajča, Jan; University Hospital Ostrava, Interventional Neuroradiology and Angiology Department Urbanec, René; University Hospital Ostrava, Surgery Clinic and Anaesthesiology Department Klement, Petr; McMaster University, Henderson Research Center Martínek, Jan; J.G.Mendel Cancer Center, Clinical Laboratory Klement, Giannoula; Harvard MU, Children's Hospital, Dana-Farber Cancer Institute
Keywords:	Critical Limb Ischemia, Diabetic Foot Ulcer, Autologous Bone Marrow Stem Cells, Lymphopenia of bone marrow

Abstract:	Fifty percent of diabetics (7% of general population) suffer from peripheral arterial occlusive disease which progresses to amputation due to critical limb ischemia (CLI). The aim of our study was to prevent major limb amputation (MLA) in this group of patients using a local application of autologous bone marrow stem cells (ABMSC) concentrate. A total of 96 patients with CLI and foot ulcer (FU) were randomized into Group I and II. Patients in Group I, n=42 (36 males, 6 females, 66.2 ± 10.6 years) underwent local treatment with ABMSC while those in Group II, n=54 (control, 42 males, 12 females, 64.1 ± 8.6 years) received standard medical care. The frequency of major limb amputation in Group I and II was

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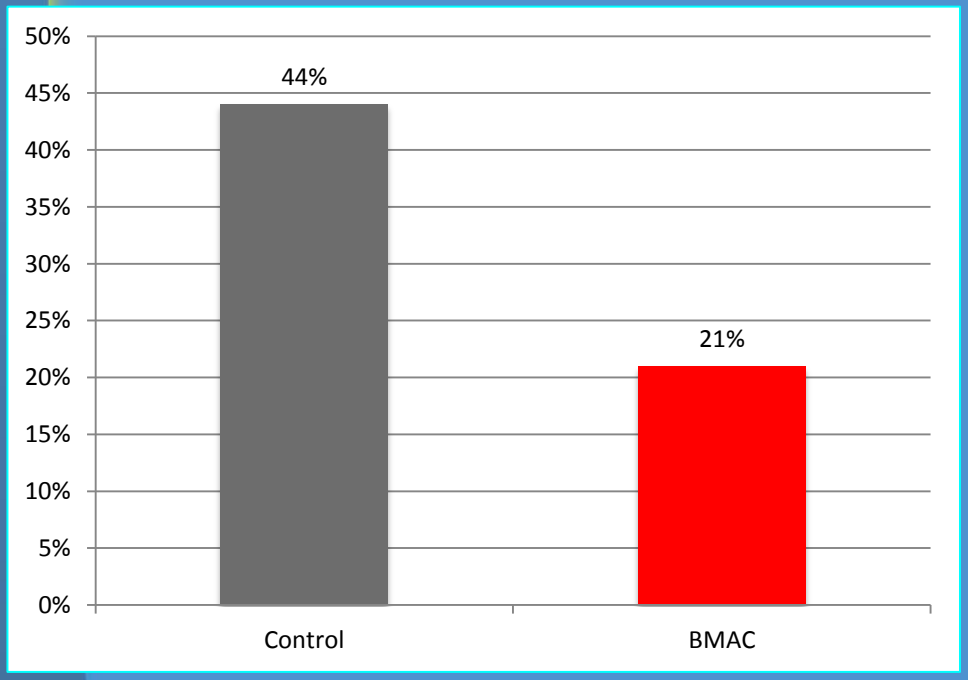
Cell Therapy, a New Standard in Management of Chronic Critical Limb Ischemia and Foot Ulcer

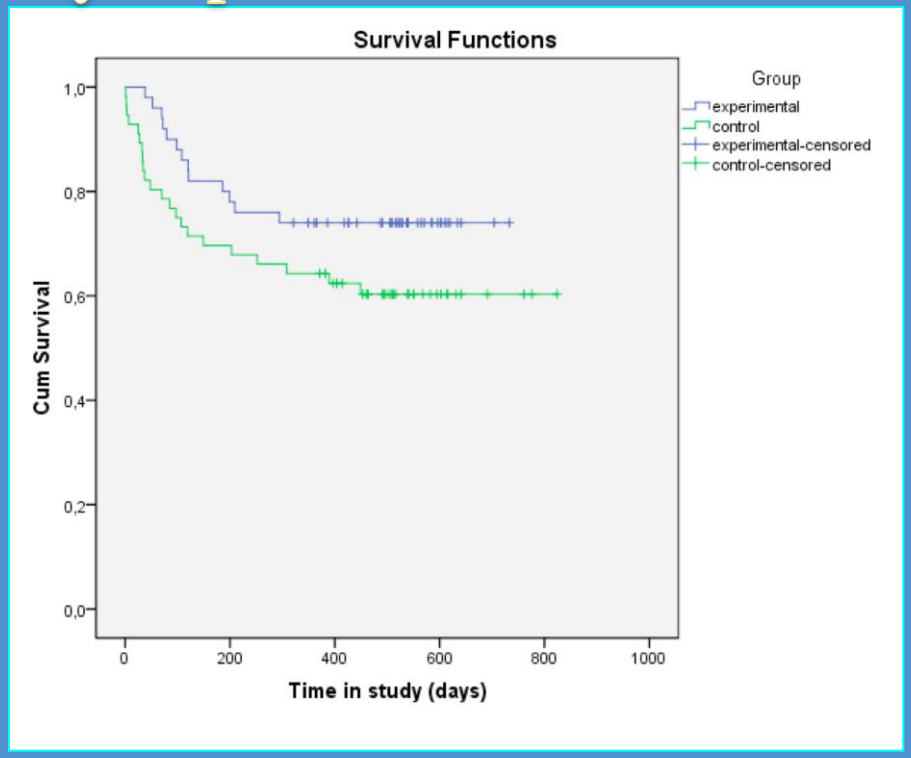
V. Procházka,* J. Gumulec,† F. Jalůvka,‡ D. Šalounová,§ T. Jonszta,* D. Czerný,*
J. Krajča,* R. Urbanec,‡ P. Klement,¶ J. Martinek,# and G. L. Klement**

ClinicalTrials.gov: NCT01232673

Amputation rate



Kaplan Meier
2y amputation free survival



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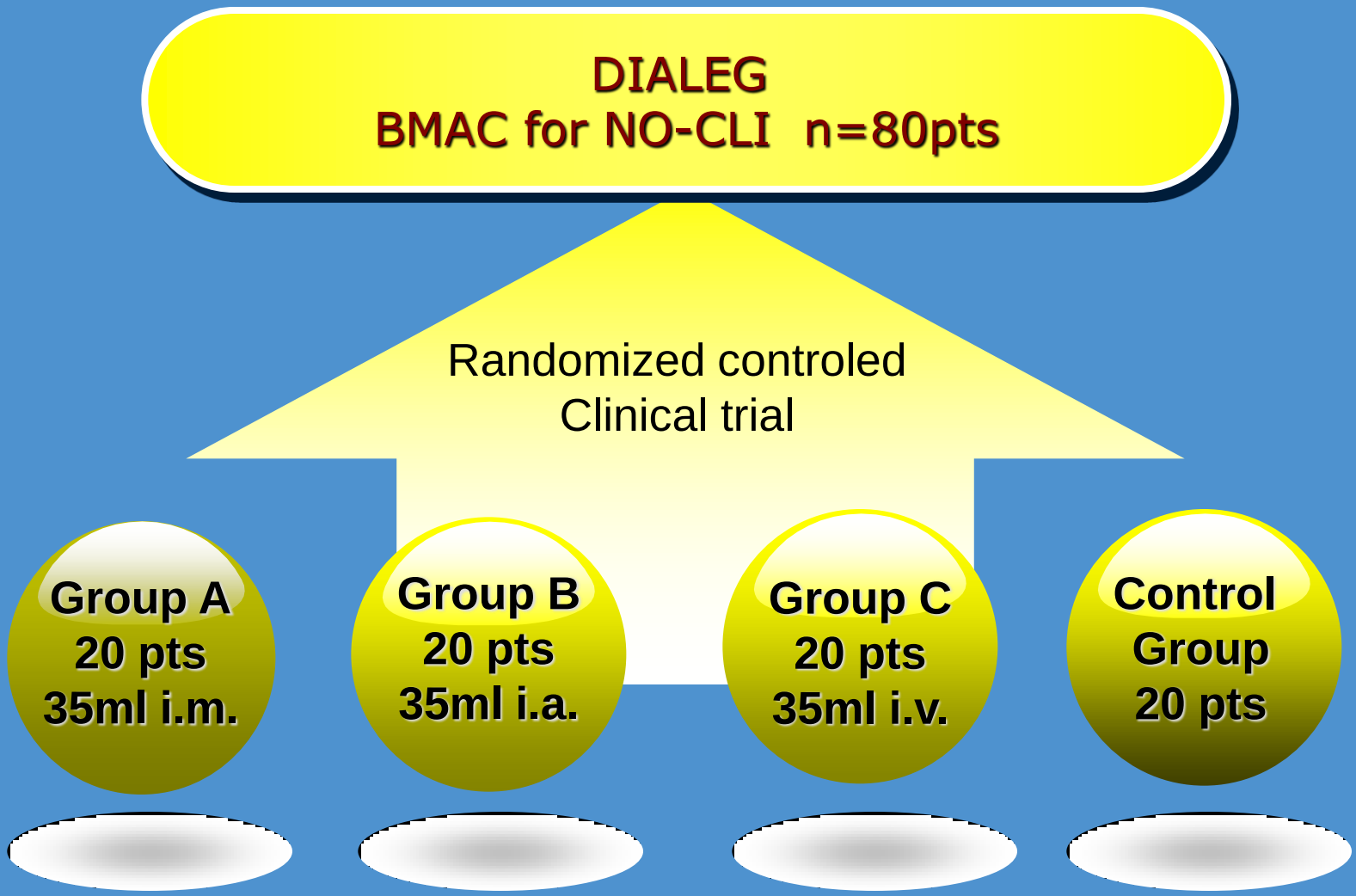

ClinicalTrials.gov Identifier:NCT01818310
sukls *102215/2012*

ASC-SVF in CLI and Foot Ulcer

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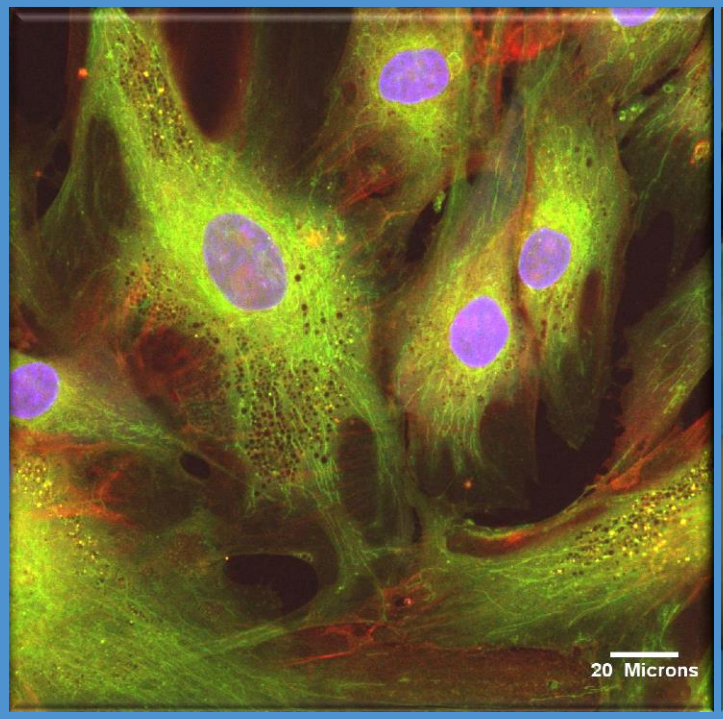
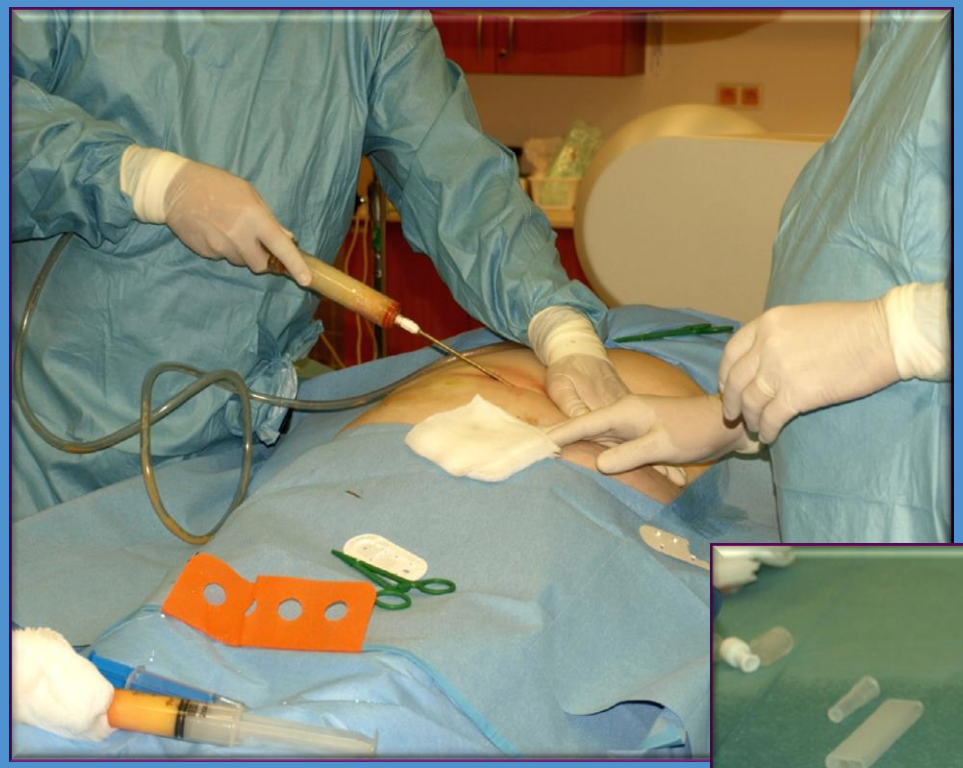
CLI and Diabetic foot treated by Autologous Adipose Stem Cells SVF - Stromal Vascular Fraction



Lipoaspiration of SVF-ADSC



60ml of fresh LPA-ADSC containes SVF with 60-70% of viable CD34+ cells

60ml Adipose tissue LPA separation – 36ml fresh ASC-SVF

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Sampling and ASC-SVF aplication

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Day 0


Day 60


Day 240


1Y

Current status - 3 year FU

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18 Patients included in the pilot registry study

- 5 Patients – MLA (Major Limb Amputation) for disease progression **(27,8 %)**
- 13 Patients - Healed & Pain reduction **(72,2%)**
- 0 Death
- 0 SAE or Liposuction AE
- 0 Lost or withdrown from study

DiaCellix – Produkty regenerativní medicíny pro léčbu sekundárních příznaků T2DM
Číslo projektu: LJ14003

4MEDi - Centrum buněčné terapie a diagnostiky a. s.

Oponentní řízení k projektu za rok 2014

Projekt LJ14003 je spolufinancován Ministerstvem školství, mládeže a tělovýchovy v rámci programu GESHER/MOST.

MINISTERSTVO ŠKOLSTVÍ, MLÁDEŽE A TĚLOVÝCHOVY

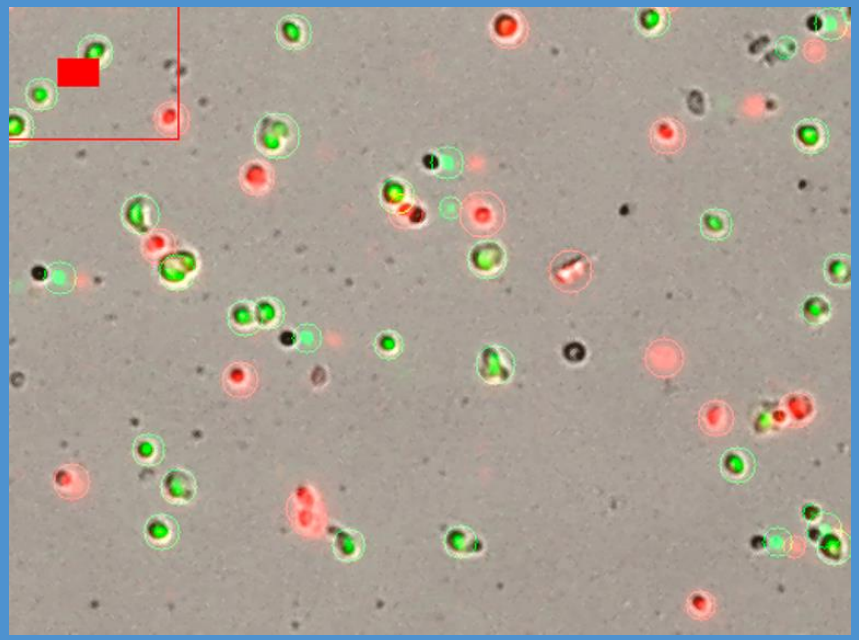

primecell

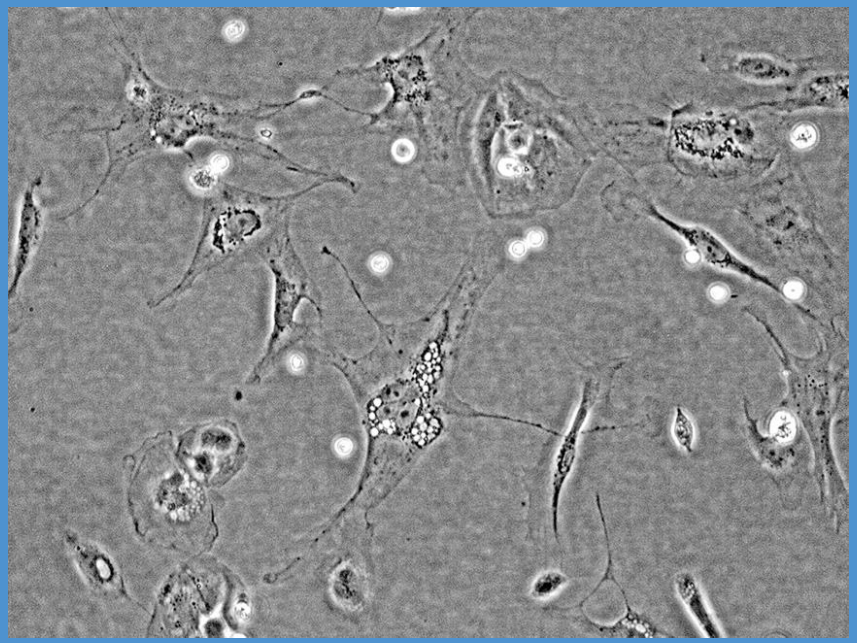
Advance Therapy Medicinal Products (ATMPs) – 4MEDi Ostrava


regenHU
3D Discovery
regenHU
3A 05

DiaCellix – Produkty regenerativní medicíny pro léčbu sekundárních příznaků T2DM

Číslo projektu: LJ14003





Hind-limb ischemia projects

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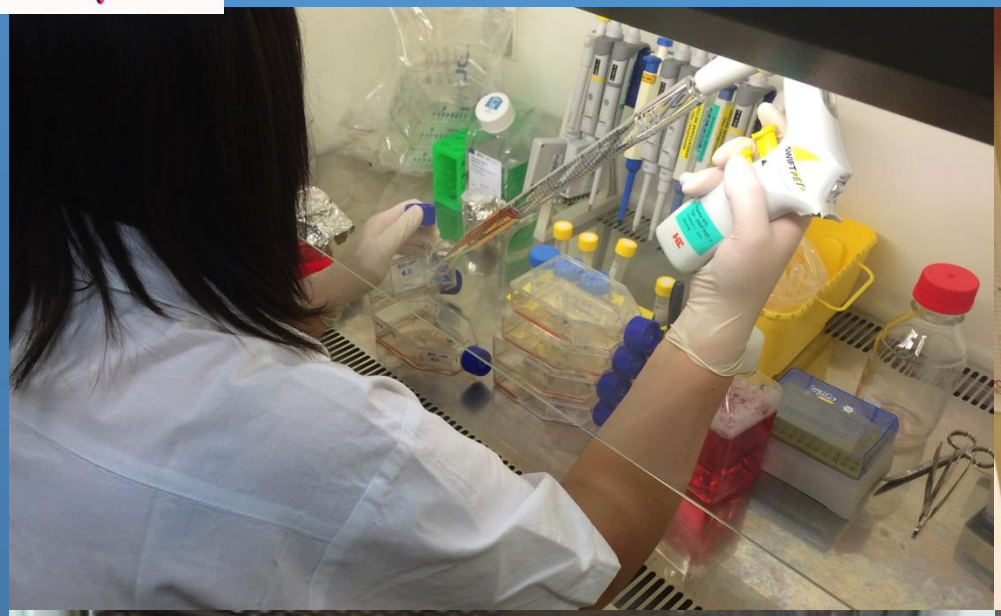
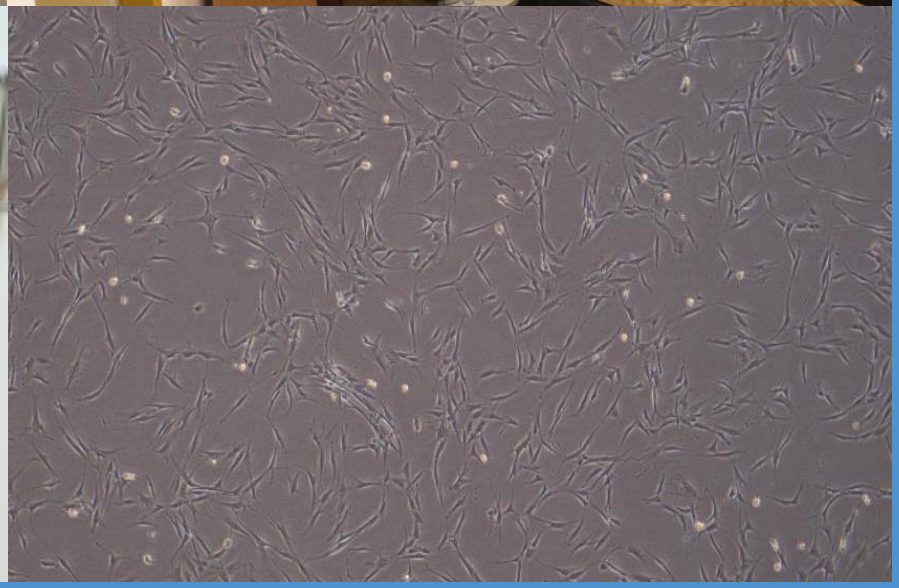
Preclinical diabetic rabbitt model of hind-limb ischemia





Hind-limb ischemia projects

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Preclinical diabetic rabbitt model of hind-limb ischemia

Hind-limb ischemia projects

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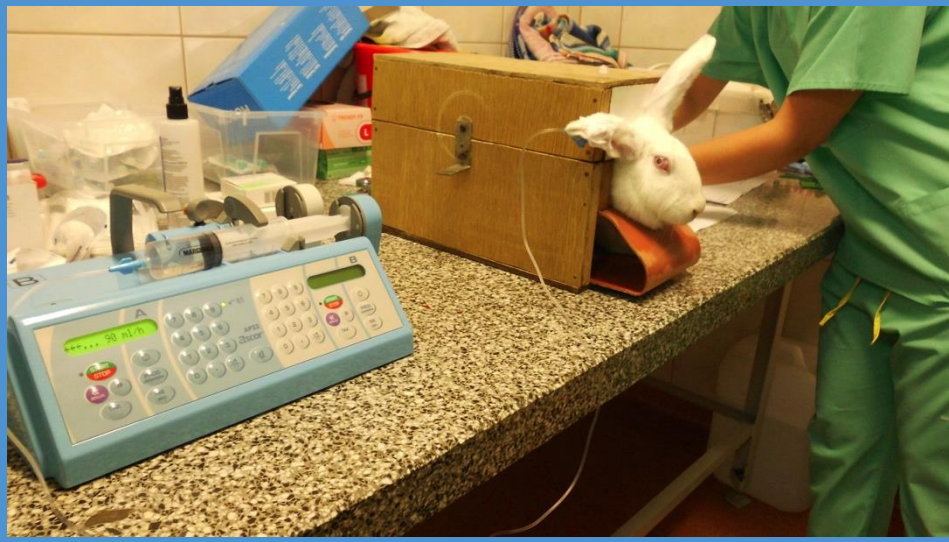
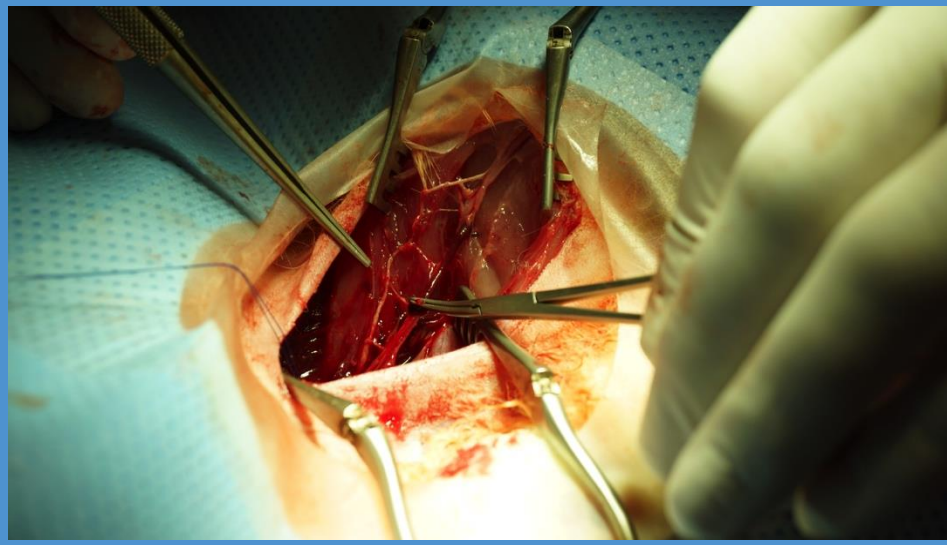
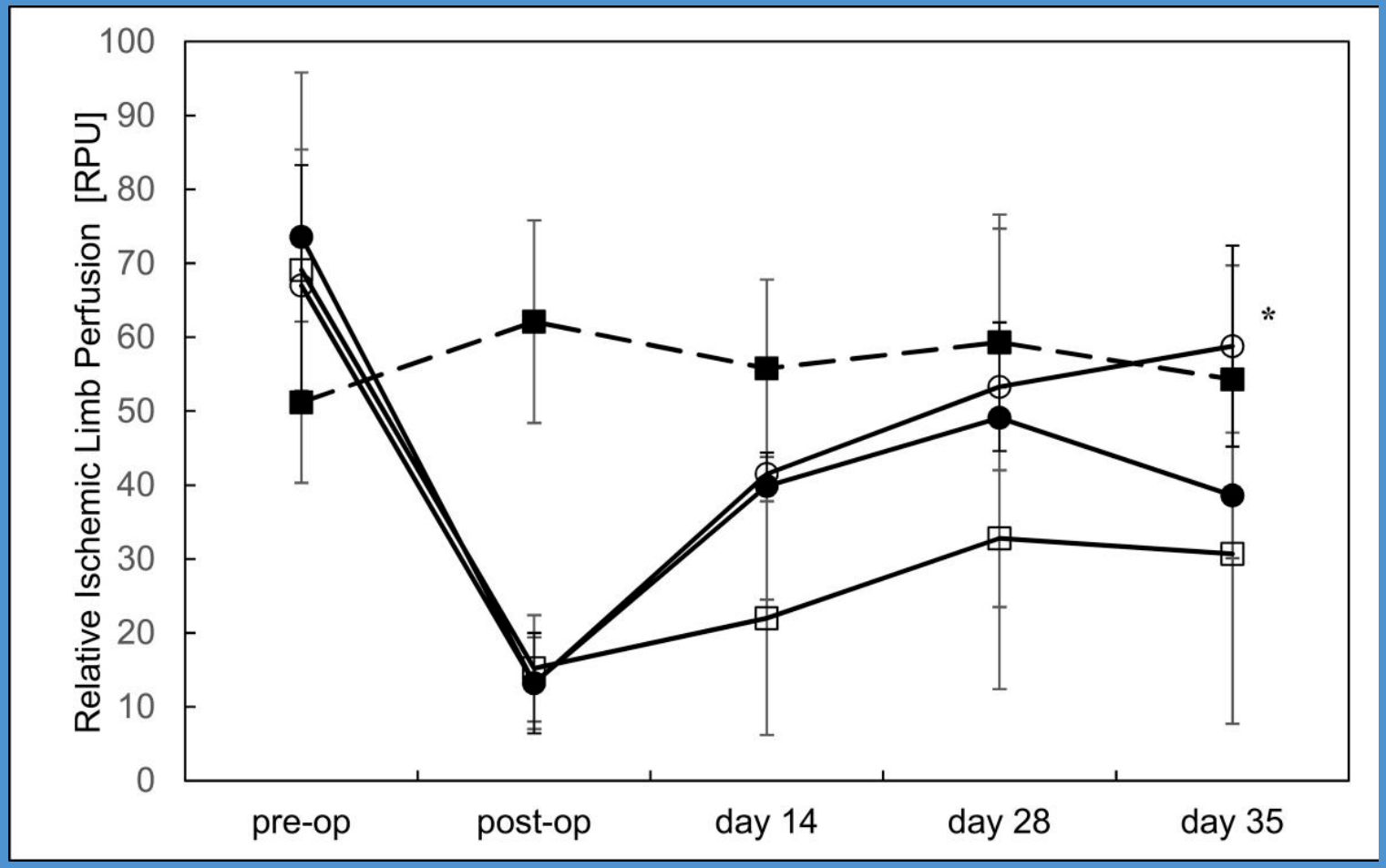




DiaCellix – Produkty regenerativní medicíny pro léčbu sekundárních příznaků T2DM
Číslo projektu: LJ14003



DiaCellix – Produkty regenerativní medicíny pro léčbu sekundárních příznaků T2DM
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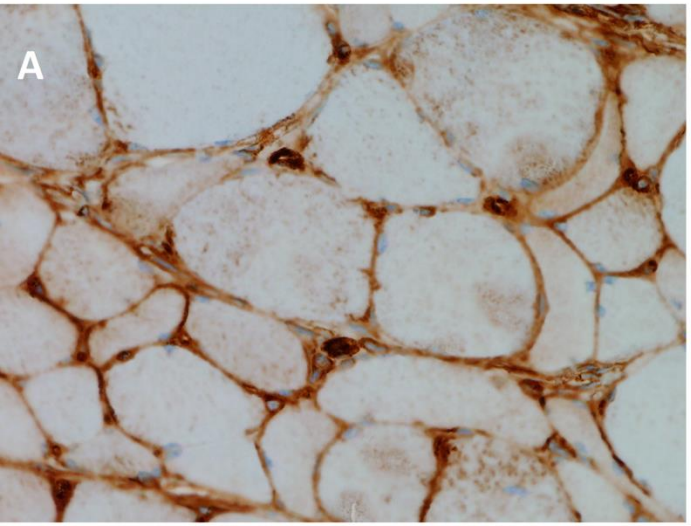

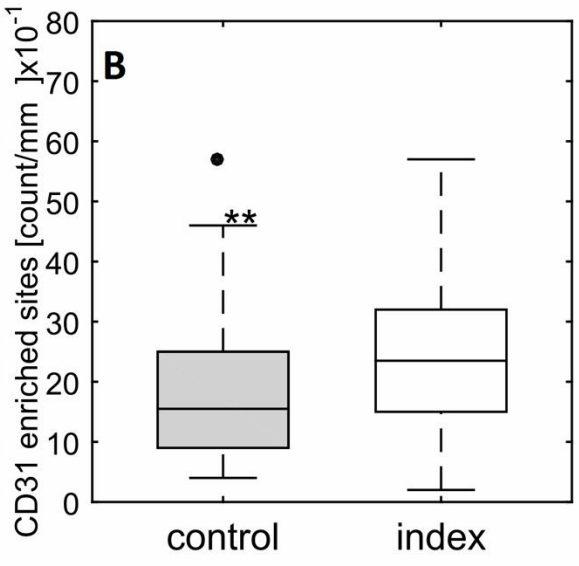

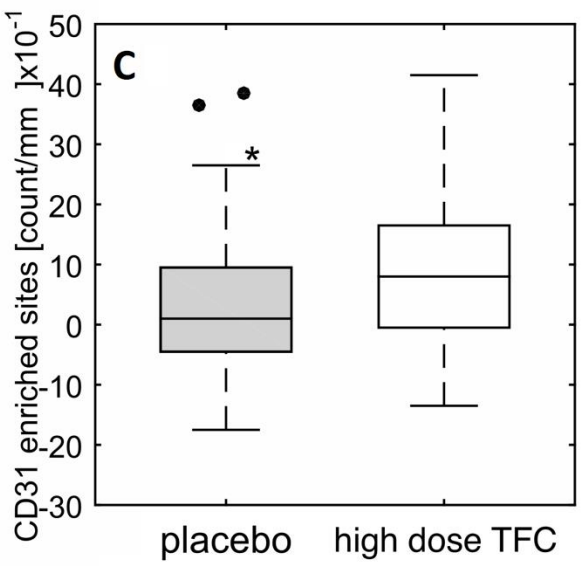

DiaCellix – Produkty regenerativní medicíny pro léčbu sekundárních příznaků T2DM
Číslo projektu: LJ14003

Therapeutic Potential of Adipose-Derived Therapeutic Factor Concentrate for Treating Critical Limb Ischemia

Authors: Procházka, Václav[1]; Jurčíková, Jana[2]; Laššák, Ondrej[3]; Vítková, Kateřina[3]; Pavliska, Lubomír[3]; Porubová, Ludmila[4]; Buszman, Piotr; Krauze, Agata[4]; Fernandez, Carlos[4]; Jalůvka, František[5]; Špačková, Iveta[6]; Lochman, Ivo[7]; Jana, Dvořáčková[8]; Merfeld-Clauss, Stephanie[9, 10]; March, Keith[9, 10]; Traktuev, Dmitry[9, 10]; Johnstone, Brian[11]

Source: Cell Transplantation (/content/cog/ct;jsessionid=5flmcrkijrda.alexandra)

Publisher: Cognizant Communication Corporation (/content/cog;jsessionid=5flmcrkijrda.alexandra)

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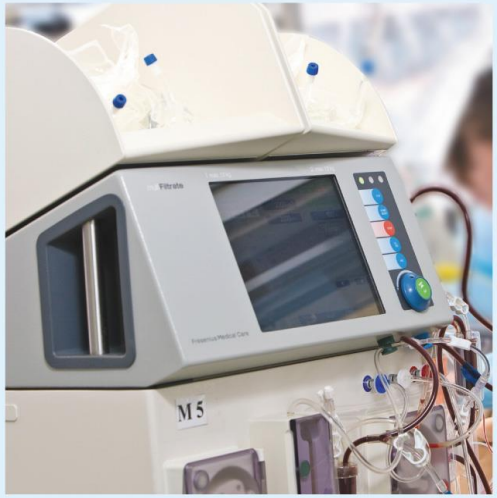
Clinical Translational Research in New Biotechnology Products



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AKREDITOVÁNO SAK AKREDITOVÁNO

Wound Healing
Small Intestinal Submucosa (SIS) Biologic Graft

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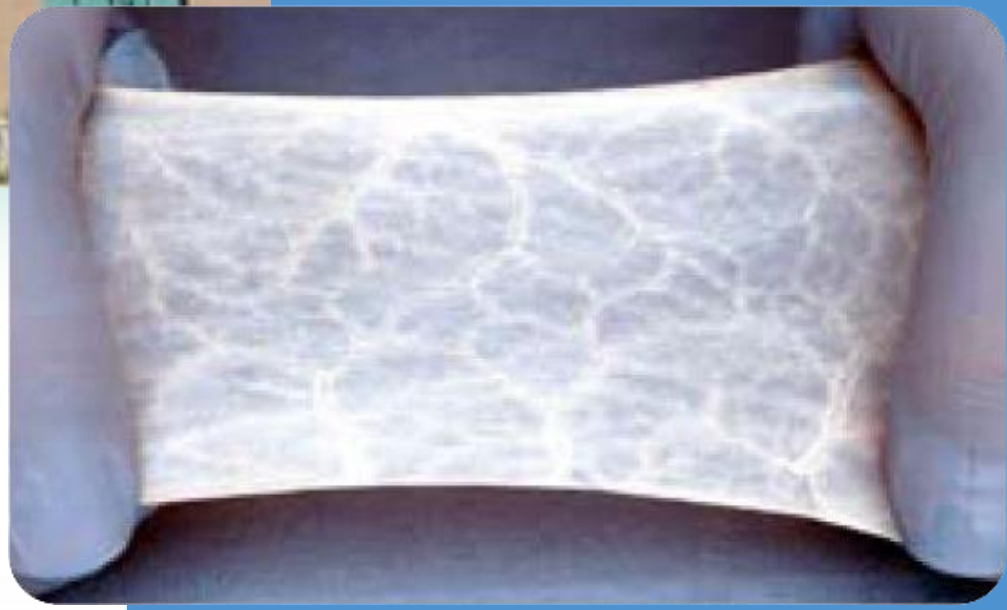
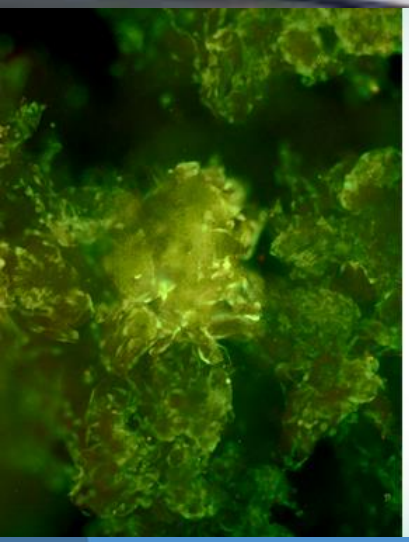




BIODESIGN
ADVANCED TISSUE REPAIR

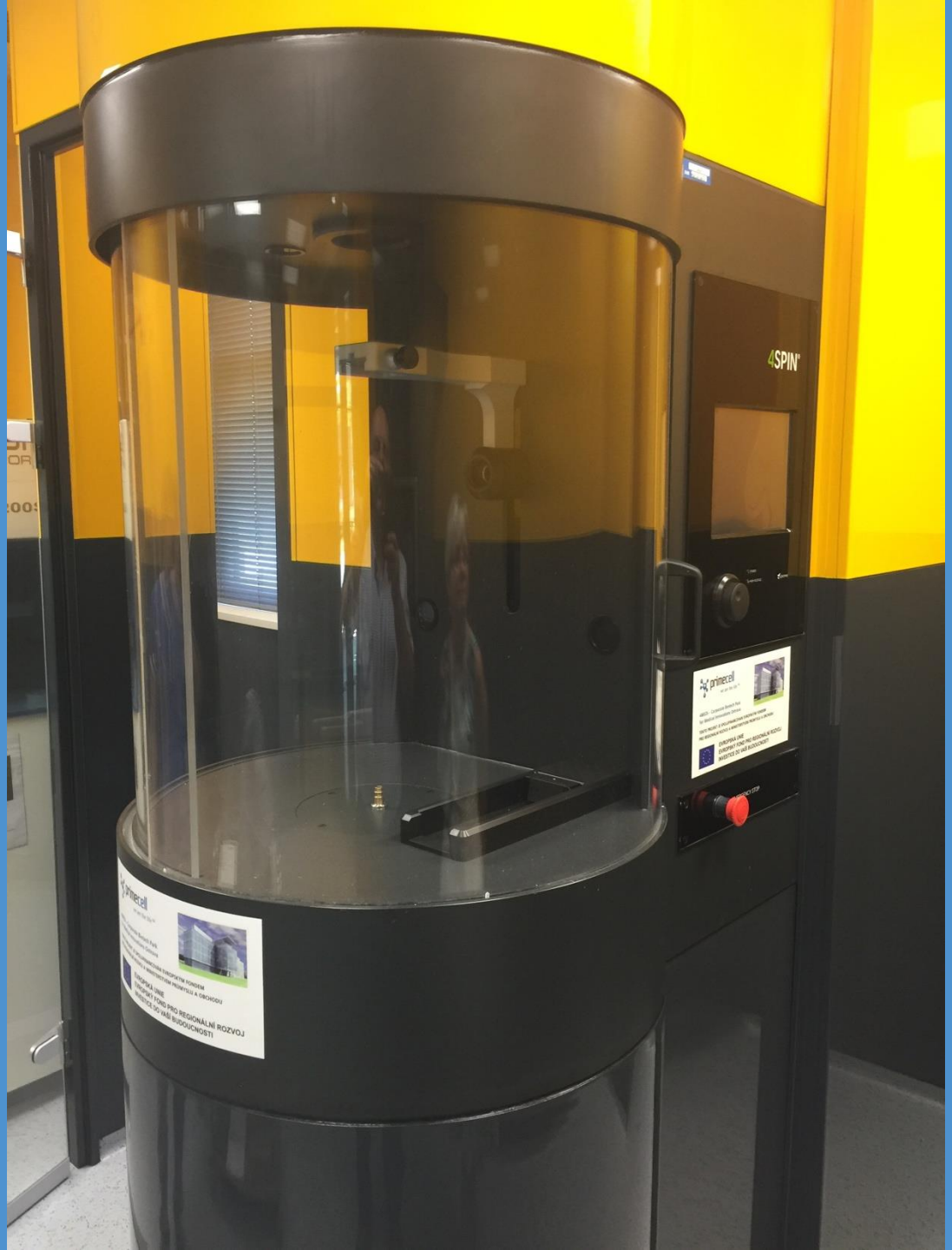
Device integration
Drug delivery
Cell delivery
Combination therapies

◀ Preclinical research of human endothelial progenitor cells growing on Biodesign particles.

No current products have received regulatory clearance for these indications.

Cook Biotech, West Lafayette,IN, USA


nanospider
Elmarco
NANO FOR LIFE
NS LAB 200S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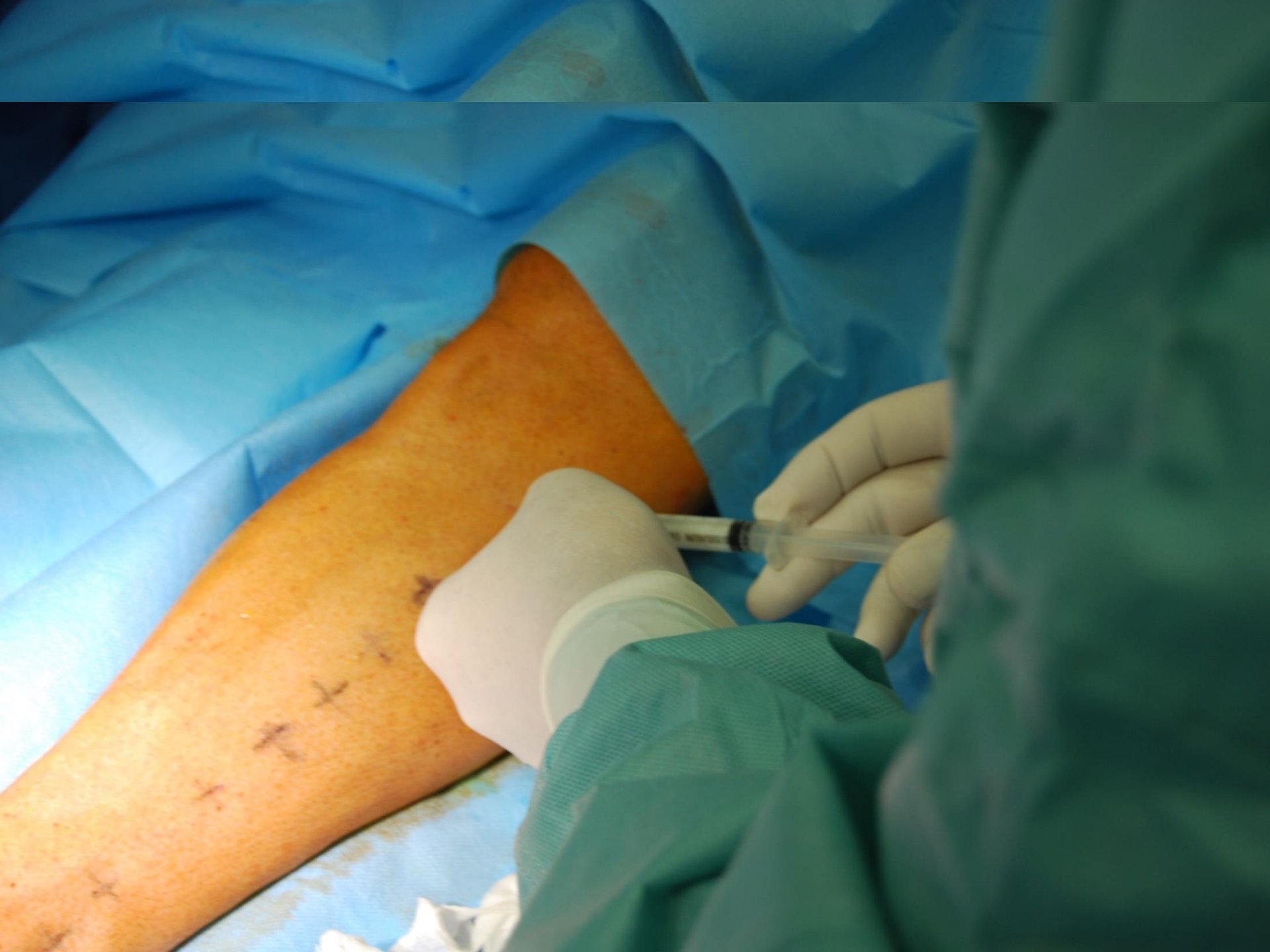
EVROPSKÝ FOND PRO REGIONÁLNÍ ROZVOJ
INVESTICE DO VAŠÍ BUDOUCNOSTI



DiaCellix – Produkty regenerativní medicíny pro léčbu sekundárních příznaků T2DM
Číslo projektu: LJ14003

4MEDi - Centrum buněčné terapie a diagnostiky a. s.

2015 – testování kombinovaného produktu

ASC-CM + SIS mikročástice

Projekt LJ14003 je spolufinancován Ministerstvem školství, mládeže a tělovýchovy v rámci programu GESHER/MOST.

MINISTERSTVO ŠKOLSTVÍ, MLÁDEŽE A TĚLOVÝCHOVY

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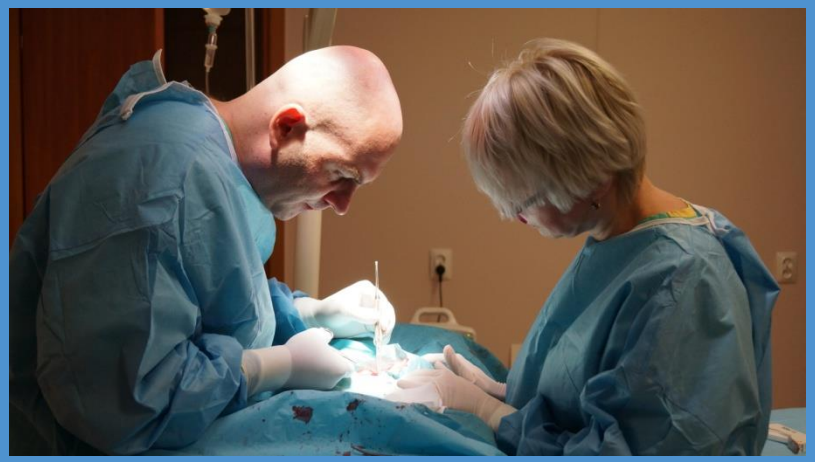
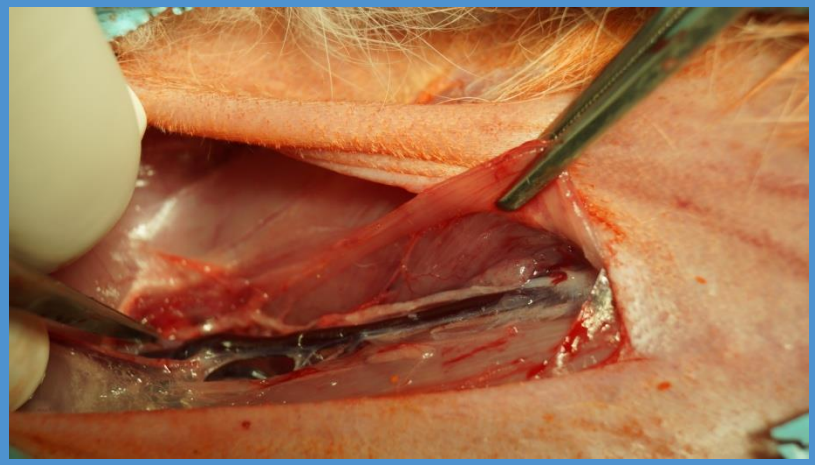
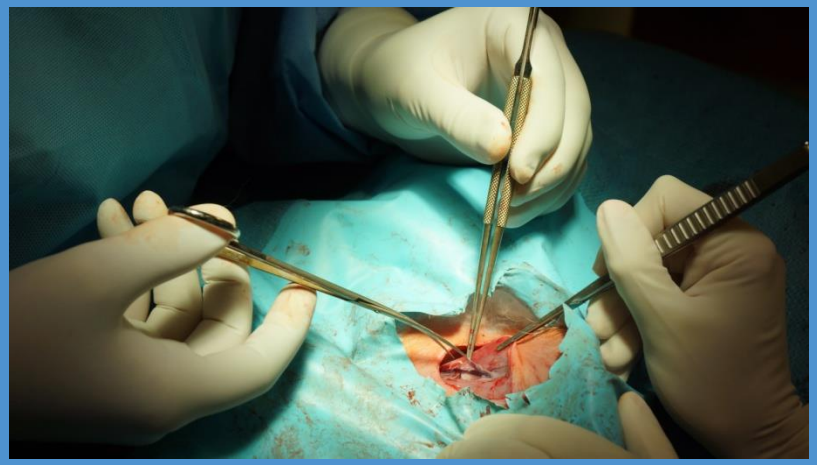
Číslo projektu: LJ14003







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MS - Biotechnology Cluster

- 4MEDI – biotechnologický park a.s.
- Fakultní nemocnice Ostrava
- Zdravotní ústav se sídlem v Ostravě
- VŠB –Technická univerzita Ostrava
- OSU - Ostravská univerzita
- E&H Services a.s.
- Walmark
- Mölnlycke Healthcare
- Spadia a.s.
- Roper Engineering s.r.o.
- Meditrade s.r.o.

Regionální inovační strategie Moravskoslezského kraje

MS - Biotechnology Cluster

Tissue Engineering

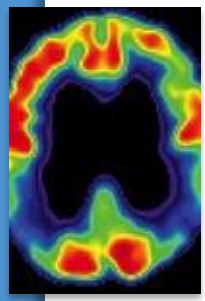
- 3D bioprinting, scaffolds
- SIS technology and matrix
- Orthopedic research: (NTC-Chondrograft)
- Cryobanking

Stem cell therapy R&D

- Biopharmacology/biosimilars/ATMP
- Critical Limb ischemia
- Treatment of Type2 DM
- ASC –CM research
- COPD, ARDS – pulmonary R&D

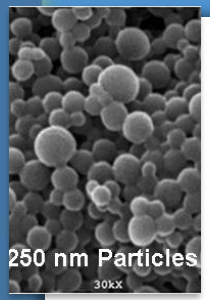
BioMed app Micro&Nano tech.

- Cell technologies
- New materials for traumatology
- Perfusion microfluidics for cell technology
- Nanomaterials (Electrospin technology)
- Nanobiosenzors



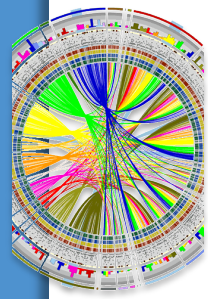
Neurodegenerative Diseases

- Farmaco-genomic studies
- ASD- Autistic spectra disorders
- ALS- Amyotrophic Lateral Sclerosis
- AD-Alzheimer disease



Bio-enviromental R&D

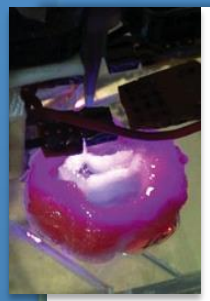
- Nano-toxicology a nano-patology:
  - Tumors research
  - Autoimune diseases
  - Genotoxicity
- Enviro-toxicity (Diabetes mellitus, Leukemia)



Bioinformatics and Data Analysis

- Robust data analysis of biomedical data
- Empiric models
  (data driven Machine Learning)
- Imaging modeling and software development
- RFID technology
- Phyziom modeling

MS - Biotechnology Cluster



Genomic analysis

- Biobanking of tumor samples
- Cancer diseases
- Neurodegenerative diseases
- Cardiovascular diseases
- Applied genomics

Pharmacology

- Personalized medicine
- Tumor oncovaccine
- Tissue culters for drug testing
- Biopharmacology/biosimilars/ATMP

Materials and Biomaterials

- 3D printing, bioprinting
- Laser technology
- New materials for Health-care
- Orthotic prosthesis

Epidemiology

- Determinants of mortality
- Cardiovascular diseases
- Cerebrovascular disease
- Cohort studies / comparative studies

Exposition studies

- Dietary expozitions
- External and Internal environment / POPS emitions, polution
- Nanoparticles
- Biological monitoring

Other studies / Interventions

- Socio-economical studies
  - Environment and employment
  - Interventions and employment
- Sources Identification / Technology
- Public awareness

Thank You !