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Acknowledgements:



GOBIERNO DE EXTREMADURA
Consejería de Empleo, Empresa e Innovación

Accredited entity:



STEM CELL THERAPY

COMPANY PROFILE & SCIENTIFIC ACTIVITIES



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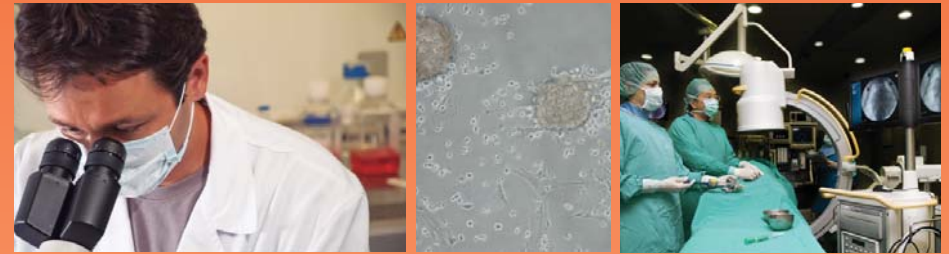


STEM CELL THERAPY

COMPANY PROFILE & SCIENTIFIC ACTIVITIES

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CELL CULTURE AND HISTOLOGICAL TECHNIQUES

- Isolation of mesenchymal stem cells
- Isolation of lymphocyte subsets
- Proliferation and cytotoxicity assays
- Adhesion, migration and invasion assays (in vitro)
- Cell culture of tumor cells, mesenchymal stem cells and lymphocytes
- Processing of tissue samples for histological examination



FLOW CYTOMETRY

- Phenotype of lymphocytes
- Proliferation analysis by CFSE
- Phenotype of myeloid leukemias and solid tumors
- Telomere length and apoptosis
- Quantification of soluble molecules by FACS
- Intracellular stainings of cytokines

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4. STEM CELL THERAPY UNIT AT JUMISC LABORATORY TECHNIQUES

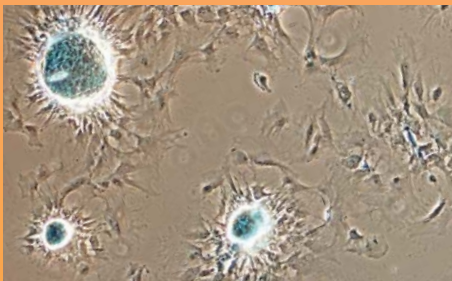


IMMUNOASSAYS

- ELISA
- Western-blot
- Immunofluorescence microscopy

MOLECULAR BIOLOGY TECHNIQUES

- Nucleic acid extractions
- Primer designing
- PCR / RT-PCR / qRT-PCR
- FISH



1. COMPANY PROFILE

ORGANISATION DESCRIPTION

The Jesús Usón Minimally Invasive Surgery Centre, JUMISC, is a multidisciplinary institution dedicated to excellence in research and training in minimally invasive surgical techniques (Bioengineering and Health Technologies, Laparoscopy, Endoscopy, Microsurgery, Endoluminal Therapy and Diagnosis, Anesthesiology, Pharmacy). Thanks to the available facilities and equipment, it is possible to develop less invasive surgical treatments by applying combined techniques and multidisciplinary equipment for treatment approach, thus benefiting the patient and providing higher precision to the surgeon. Similarly, the Centre is committed to technological development and innovation in health care, and for its advancement it works closely with companies from all over the world. Besides, since the JUMISC is free from medical assistance, it joins all its efforts and resources into research. In short, this activity will have an impact on higher clinical quality for human patients and on the scientific and technical development within medical/surgical areas.

The latest generation equipments and facilities are available at the Centre, allowing for the highest possible level of research and training for medicine and surgery professionals worldwide and positioning it as a global leader in health applied technology.

The Centre has been awarded the following accreditations, among other:

- Quality assurance certified by AENOR (ER-0430/2002) according to the UNE-EN-ISO 9001:08 standards for "The design of applied research projects and in the theoretical and practical training in minimally invasive surgical techniques".
- GLP Compliance Certificate (No.: BPLI 11.04/001 MSC). This certification confirms that the JUMISC is able to carry out studies of In Vivo Toxicity, Tolerance and Pharmacodynamics of medicinal products, in both human and veterinary medicine.

Covering a total area of 20.200 square meters, the JUMISC is divided into four different spaces: surgical area, offices space, events and congresses and residential area.

The surgical area has 10 experimental operating theatres with State-of-the-Art equipment including a fluoroscope, CT scan, an MRI system, etc. integrated with advanced telecommunication systems. A dedicated animal housing facility and two clinical conference rooms complement these facilities, perfectly adapted for the highest level of surgical training and research.

MAIN ATTRIBUTED TASKS

JUMISC will focus on:

- 1) Definition of minimally invasive surgery use case scenarios
- 2) Intervention workflow and surgical procedures knowledge
- 3) Close collaboration with technological partners to assure clinical acceptance of developments
- 4) Clinical validation and testing

RELEVANT SKILLS AND PREVIOUS EXPERIENCES

The JUMISC involved a sequential model of accredited training and an exceptional environment for surgical training, with attendants from more than 40 countries around de world, with over 100 training activities every year and more than 1350 attendants. Since 1999, the JUMISC has developed more than 100 regional, nationals and international projects based on collaboration between public and private institutions and since 2003, more than 270 scientific papers, many of them published in journals indexed by Thomson Reuters.



2. SCIENTIFIC ACTIVITIES AT THE JUMISC

The JUMISC gears the development of its activities towards serving society. Therefore, in addition to the direct benefits derived from an adequate education and the training of health professionals through technological dissemination, R&D also generates extraordinary achievements of social interest, contributing to increased knowledge and use of technology related to minimally invasive surgery and other fields of health. Among the various lines of work proposed by RDI public groups and private Centre users specifically relate to:

- New types of sutures for paediatric patients, allowing the longitudinal and transverse growth of vessels during the growth phase, as well as the advantage simple and quick application.
- Research for the treatment of morbid obesity, still in the pilot phase, involving the implantation of a laparoscopic electrostimulator, which emits pulses, resulting in a decrease in food consumption and therefore weight. In the future this would represent a new therapeutic option for obese patients, being reversible, less invasive and a short operative time.
- Valuation of the osteointegration ability of different biomaterials for orthopedics and traumatology.



- Development of navigation systems and surgical planning based on virtual reality simulators and simulations aimed at optimizing the physical learning period of minimally invasive surgery.
- Evaluation and development of new types of stents in the treatment of urethral structures.
- Rating aortic clamping times on hemodynamic variables in replacement aortic laparoscopic surgery and conventional monitoring of the autonomic nervous



system; pediatric ventilation, and building a compartment syndrome model.

- Surgical simulation, virtual reality and usage of medical imaging, employing the latest technological advances for the training of qualified surgical professionals, allowing earlier training in surgical intervention, in anticipation of potential unpredictable events.
- Development of new materials, instruments, equipment and surgical protocols, etc.
- Experimental modeling of different pathologies (aortic aneurysm, prostate disease, acute and chronic myocardial infarction, etc.).
- Application of gene therapy in the treatment of chronic myocardial ischemia.

The R&D activities are divided in several Units as: Anaesthetics Unit, Bioengineering & Health Technology Unit, General Surgery Unit, Endoluminal Therapy and Diagnosis Unit, Endoscopy Unit, Laparoscopy Unit, Microsurgery Unit, Stem Cell Therapy Unit, Management Service, Research Animal Resources, Pharmacy Service, Computer Science, Image Processing-Communications



differentiation of the endogenous CSCs. Moreover, since 2011 the JUMISC is involved in three different projects for the treatment of osteoarthritis diseases using adult stem cells and scaffolds. Finally, the JUMISC collaborate with biopharmaceutical companies to improve the implantation and immunomodulatory role of mesenchymal stem cells.

In summary, the main goal of the Stem Cell Therapy Unit at JUMISC is to promote the participation of the JUMISC in cell-based preclinical trials and aims to become a platform for translational research to enable accurate translation from preclinical research to clinical practice.

3. STEM CELL RESEARCH AT THE JUMISC

is developing new therapies that combine the use of adult stem cells with minimally invasive surgery techniques. For this research, the JUMISC has set up a fully equipped laboratory for the isolation, characterization and expansion of adult stem cells. The Stem Cell Therapy staff is composed by two doctors, one research technologist and a laboratory technician. These researchers are experienced to manage the experimental protocols and have demonstrated experience in cell cultures, in vitro and in vivo assays as well as in surgical procedures.

At the present, the JUMISC is currently involved in several projects based on stem cell therapy for cardiovascular and osteoarticular diseases. Regarding to cardiovascular diseases, the JUMISC is currently involved in the European project CARE-MI (Cardio Repair European Multidisciplinary Initiative) developing the preclinical safety testing for myocardial regenerative therapies based on the in situ activation, multiplication and

“ the JUMISC is involved in several projects based on stem cell therapy for cardiovascular and osteoarticular diseases ”

“ JUMISC is a multidisciplinary institution dedicated to preclinical research ”



3. STEM CELL RESEARCH AT THE JUMISC

Adult stem cells are a useful clinical tool as treatment for the treatment of many diseases. Stem cell-based therapy has demonstrated their potential for the treatment of various diseases as diabetes, spinal cord injury, Huntington disease, multiple sclerosis, ischemia, rheumatoid arthritis, skin regeneration, glioblastoma, colitis, graft-versus-host disease, Crohn's disease and cardiovascular diseases. At the present, the success in some of the clinical trials has been modest and adult stem cells have not worked out as well as hoped. Apparently, some of these disappointing results are possibly due to inadequate preclinical testing.

“ the Center has fully equipped laboratory for stem cell research ”

The preclinical research is a building block for increasing the understanding of stem cells biology and plays a critical role to predict the efficacy of adult stem cells in clinical trials. In order to test the efficacy of adult stem cells, several preclinical models have been developed in the last decade. Most of these preclinical studies were conducted in murine models; however, significant anatomical and physiological differences exist between mice and humans which limit their extrapolation in clinical trials. Preclinical trials in large animals is a significant step for future treatments in humans being a necessary step to evaluate the safety, feasibility, dosage, engraftment and toxicity of adoptively transferred cells.

Large animal models have been used to predict outcome of clinical trials in stem cell research and have been used for ischemic heart disease and hematopoietic stem cell



gene therapy. The anatomic similarities between swine and humans make this animal model more attractive than small animals to test the safety and efficacy of adult stem cells. In particular, this animal model has been widely used in cardiac stem cell research for the treatment of acute and chronic myocardial infarct.



The JUMISC is currently focused on the creation and validation of suitable animal models to assess the applicability, effectiveness and benefit of stem cells in the treatment of myocardial ischemia and other diseases. In this sense, the JUMISC