Centre of Biocompatibility
Foundation for Cardiac Surgery Development

19 Sep 2019 - 20 Sep 2019
Tuebingen, Germany
Foundation for Cardiac Surgery Development

The Centre of Biocompatibility will be established on the basis of Foundation for Cardiac Surgery Development (FCSD) and cooperating institutions. FCSD is a non-state, non-commercial, high-technology research and implementation institution, working to improve the tools and methods of treatment of the most serious heart diseases and to introduce them to clinical practice. The Foundation’s research and scientific activity is interdisciplinary in nature and includes i.e. topics in the field of biomedical engineering, heart prosthetics design, medical robotics and tissue engineering.
Institute of Heart Prostheses

Artificial Heart Laboratory

- Development of Polish heart prostheses (POLTAH, POLCAS system and new ReligaHeart family: RH EXT, RH PED, RH ROT)

Biocybernetic Laboratory

- Robin Heart System - a family of Polish robots for soft tissue surgery

Bioengineering Laboratory

- Development of the Polish biological heart valves

Address: 41-800 Zabrze; Wolności Street 345a; tel: +48 32 3735660, fax: +48 32 3735665; romankustosz@frk.pl; www.frk.pl
In vitro functional tests of medical devices performed in Artificial Heart Laboratory

Blood infusion set test regarding blood damage or interaction

Infusion pump test regarding blood damage or interaction

<table>
<thead>
<tr>
<th>Variable</th>
<th>grupa T2/0 (before transfusion)</th>
<th>grupa T2/1 (after 10x transfusion)</th>
<th>grupa T2/2 (control autohemolysis)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCT [%]</td>
<td>38.4</td>
<td>37.0</td>
<td>38.5</td>
<td>0.0053</td>
</tr>
<tr>
<td>MCV [fL]</td>
<td>82.5</td>
<td>83.0</td>
<td>83.3</td>
<td>0.0105</td>
</tr>
<tr>
<td>HGB [g/L]</td>
<td>0.2</td>
<td>0.3</td>
<td>0.9</td>
<td>0.0000</td>
</tr>
<tr>
<td>K [mmol/L]</td>
<td>5.3</td>
<td>5.1*</td>
<td>5.2*</td>
<td>0.0024</td>
</tr>
<tr>
<td>LDH [U/L]</td>
<td>817</td>
<td>1019</td>
<td>922</td>
<td>0.0000</td>
</tr>
</tbody>
</table>
Hemocompatibility assessment tests

Biomaterial induced haemolysis in direct contact with whole human blood

Blood contacting devices hemolysis analysis (Rotary blood ventricular assist device – ReligaHeart ROT)

Rapid thrombogenesis test of blood contacting devices (ReligaHeart ROT)
Animal study of medical devices

Rotary Pump construction Biomaterial (Titanium coated TiN) on 26 weeks after implantation

Rotary pump implant to sheep (REligaHeart ROT)

Rotary Pump construction Biomaterial (Titanium coated TiN) on 52 weeks after implantation

Anatomical evaluation of pump location in sheep heart (ReligaHeart ROT)
Main cooperating Institutions

Silesian Medical University Centre of Experimental Medicine

Foundation for Cardiac Surgery Development

Centre of Polymer and Carbon Materials Polish Academy of Science

Silesian Medical University Department of Histology and Cell Pathology
Experimental Medicine Centre of Silesian Medical University – Centre facility in Katowice
AFM Image of bionanocelulose after contact with platelet rich plasma

Histochemical analysis on systemic toxicity on kidney (left) and spleen (right)

Immunohistochemical analysis of blood contacting devices

Histochemical analysis on blood contacting surface of oxygenators
Infrared Spectroscopy with Fourier Analysis (FTIR)

Gel Chromatography (GPC)

Thermogravimetry (TGA)

Scanning electron microscopy (SEM)
Goals and needs:

• Creation of a central biocompatibility centre basing on the research facilities of the Artificial Heart Laboratory in Foundation for Cardiac Surgery Development;

• Establishment of a highly specialized network consortium of institutions providing biological assessment services for new medical devices and biomaterials;

• **Implementation and standardization of new in vitro biocompatibility assessment methods to replace and limit animal testing.** Establishment of in vitro analysis with a new partner to introduce cytotoxicity, genotoxicity, irritation and pyrogenicity test to reduce tests on small animals, Heamocompatybility research methods development - to reduce the preclinical analysis of blood contacting medical devices on animals;

• Creation of a comprehensive research offer;

• Purchase of new research equipment (e.g. spectrophotometer UV VIS, confocal microscope; flow cytometer, gasometer, hematological analyzer, HPLC, DSC);

• Improvement and development of new methods in the field of heamocompatibility of medical devices dedicated to contact with blood;

• Introduction of a quality management system for testing laboratories based on PN EN ISO 17025;
Research offer:

- Classification of medical devices and analysis of medical devices requirements according to MDD (MDR in near future)
- Determining the research plan of a new medical device according to the guidelines of PN EN ISO 10993
- Development of a risk analysis for the introduction of a new medical device for clinical use, according to ISO 14971 standard
- The conduction of biocompatibility tests in accordance with PN EN ISO 10993 guidelines and related standards.
- Assistance in designing animal experiments and consultations when completing the application to the Local Ethics Committee.
- Hydrodynamic tests of medical devices.
- Research on the safety of medical devices.
- Clinical tests management of medical devices.
- Assistance in the implementation of the 13485 standard and active maintenance of the certificate.
Thank you for your kind attention!