



Suspended Life - Stem Cells: Are Treatments Possible?

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The aim of this meeting, organized by the Italian no-profit associations Stampa Rossoblù, Sicilia Risvegli Onlus, Niemann Pick Onlus, Omphalos, Organizzazione Sindrome di Angelman (Or.S.A.), Cancellautismo, Marco e Andrea Tremante Foundation, was to confer regarding today's state-of-the-art and novel findings on stem cell research and applications in Italy. The meeting was held in the city of Grottammare – Ascoli Piceno County, under the auspices of Luigi Merlo, the Major of the city, and Piero Celani, the County President.

Stem cells represent promising therapeutic potential in regenerative medicine. Several untreatable human diseases could be treated by the use of different types of stem cells.

Several international experts gave interesting keynote lectures to better cover the full spectrum of stem cell useful applications. The speaker for the first key lecture was Dr. Gianfranco Merizzi (Medestea Stem Cells). He gave a detailed explanation of the role of mesenchymal stem cells (MSCs) in regenerative medicine. Cell based medicines are the main goal of the Medestea Group [1]. This R&D Company is developing MSC based drugs under good manufacturing practice (GMP). These drugs will offer important applications in allogenic cell transplantations.

Dr. Dario Siniscalco (Second University of Naples, Italy) was the second keynote speaker. He described the potential use of stem cells in treating autism. Autism spectrum disorders (ASDs) are severe heterogeneous neuro-developmental disorders characterized by dysfunctions in social interaction and communication skills, in addition to repetitive, restrictive and stereotypic verbal and non-verbal behaviours [2]. Current pharmacological treatments are directed only at the associated behavioural symptoms, without affecting all core symptoms of ASDs [3]. The particular immune and neural dysregulation observed in ASDs indicate that stem cell therapy could offer extraordinary potential as a treatment modality. The self-renewal ability with the capacity to generate more identical stem cells, the capacity to give rise to more differentiated cells, and the paracrine regulatory functions are stem cell properties that make them potential therapeutic agents for ASDs [4].

Professor Davide Vannoni (Stamina Foundation, Italy), the third keynote speaker, described the use of MSCs in treating severe human diseases. He reported the experience of the Stamina Foundation,

an Italian research institute that provide stem cell based cures for untreatable pathologies, such as spinal muscular atrophy (SMA), amyotrophic lateral sclerosis (ALS), and other fatal injuries [5]. Stamina Foundation is also devoted to disseminate the culture of the regenerative medicine in Italy, a country where stem cell applications are still in their infancy.

The lawyers Dario Bianchini and Marco Vorano (Court of Venice, Italy) reported interesting information about the current legislative aspects of stem cell transplantation in Italy. This topic gains much attention. Nowadays, in this Country the only way to undergo to stem cell treatment is being offered by the state law “Turco-Fazio” (Italian Ministerial Decree 12/05/2006). This legislation authorizes cell based therapies only as compassionate use. Indeed, the state-of-the-art on stem cell therapy in Italy is still developing and often confusing. To avoid false hoping and expectative in general population, there is a real necessity of a specific and up-to-date law. Another current debate is the question regarding the exact definition of stem cell. It seems that Italian government considers stem cells as drug. It is noteworthy to consider that stem cells are not drugs, as they are biologically active organisms. Given that, the procedures and techniques for their preparations should be considered as good laboratory practices (GLP) and not GMP.

The meeting gave the opportunity to several parents to witness their experiences with their sick relatives. Gianpaolo Carrer, Antonio Corbisiero, Giuseppe Camiolo, Irene Sampognaro, Tommaso Prisco, Arturo Folgore, Vito Tortorelli, Giorgio Tremante and Luigi Bonavita gave explanations on: i) how their relatives have been positively already treated with MSCs by Stamina Foundation and the needs of further cell based treatments; ii) the request to Italian Health Ministry for authorization for stem cell transplantations. Irene Sampognaro requested to Italian Health Ministry the authorization to treat her husband, actually in a comatose state after a tooth surgery, with MSCs produced with Stamina Foundation's protocol. Her request was very dramatic as she feels to authorize euthanasia in case of negative response by the Ministry.

Dr. Desireè Sampognaro (University of Catania, Italy) described the current situation about bioethics committees that must approve every stem cell treatment proposal.

Prof. Luca Tosoni and father Armando Moriconi elucidated the ethical questions regarding the regenerative medicine. Their talks were extremely actual and interesting. The position of Catholic Church about stem cell research and applications was also described. According to the Pope, embryonic stem cells studies and applications are not allowed, whereas adult stem cells (including mesenchymal and fetal stem cells) are encouraged [6]. However, beyond ethical concerns, it is well known the potential risk of tumour formation of embryonic stem cells [7].

Dr. Marino Andolina (former director Center for Transplantation and Cellular Therapy, Burlo Garofalo Hospital, Trieste, Italy) reported his experiences in treating several pathologies with stem cells. He has a great experience in bone marrow transplantation and in tissue and cell therapy in humans [8]. Thanks to MSC and hematopoietic stem

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cell transplantations he performed with Stamina Foundation, several young patients affected by SMA, ALS, multiple sclerosis, Niemann-Pick disease and others, including autoimmune pathologies, benefited from stem cell therapy, gained an impressive increase in the quality of their life.

As concluding remarks, the meeting highlighted the needs to increase stem cell therapeutic options by the Italian Health Ministry. Current situation regarding stem cell transplantation in Italy is difficult. Health Ministry has adopted a panel of experts to check efficacy and safety of cell therapies. However, many concerns are still debating. The board should be formed by proven experts in the stem cell field and formed not only by stem cell basic and applied researchers, but also by experts in bioethics. It is of primary importance that the board of experts is formed on the basis of scientific merits (i.e. publications), expertise in stem cell biology research and experience in cell transplantation.

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