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Cryopreserved or Fresh Therapeutic Mesenchymal Stroma Cells? Past, Present and Future.

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Abstract

Biobanking and stem cell technologies comprise a highly innovative multibillion-dollar market. Greater attention is needed to ensure that new cryobanked products and applications are fit for purpose, which is particularly important for novel cryobanked cellular therapeutics. Mesenchymal stem cell (MSC)-like advanced therapy medicinal products (ATMPs) are tested in hundreds of clinical trials, but few have progressed to efficacy evaluation so far. Results from first phase III clinical studies indicate that the implementation of 1st generation MSC-like ATMPs is hampered by high costs and suboptimal therapeutic efficacy. Failure analysis to understand the discrepancy between encouraging preclinical data and at times modest clinical performance is ongoing. This is hampered by MSC's highly complex mechanisms of action, involving multiple immunomodulatory and regenerative mediators and pathways. Thus, mayor efforts to refine potency assessment are currently underway. Great uncertainty exists considering the predominant use of log-phase culture-derived "freshly-harvested" cells in preclinical assessment versus the favored use of cryobanked "freeze-thawed" cells in the clinical setting. Another major confounder is the frequent use of minimal-expanded MSCs in academic trials versus highly expanded MSCs in many industry-sponsored studies. An explosion of literature comparing the efficacy of fresh and frozen cells underlines the relevance of this topic. We appear to witness a translational bottleneck in up-scaling preclinical assessment to clinical operations. Development of optimized next-generation MSC-like ATMPs may allow for harnessing MSCs full therapeutic potential in the future.



Image

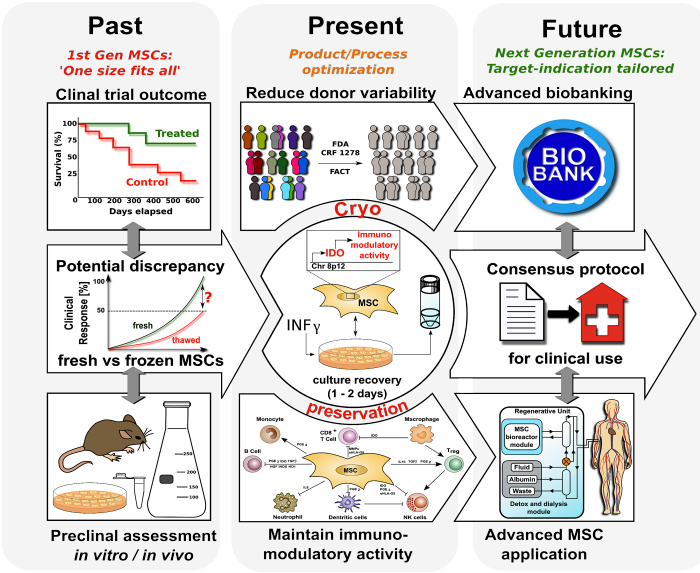


Figure 1: Outlook on the past, present and future of MSC therapy: integrating cell production, potency assessment and clinical delivery.

Recent Publications

1. Moll G et al. (2012) Are therapeutic human mesenchymal stem cells compatible with human blood? Stem Cells 30(7):1565-1574.
2. Moll G et al. (2014) Do cryopreserved mesenchymal stromal cells display impaired immunomodulatory and therapeutic properties? Stem Cells 32(9):2430-2442.
3. Hoogduijn MJ & Moll G & Bann C (2016) Effects of freeze-thawing and intravenous infusion on mesenchymal stromal cell gene expression. Stem Cells and Development 25(8):586-597.
4. Moll G & LeBlanc K (2015) Engineering more efficient multipotent mesenchymal stromal (stem) cells for systemic delivery as cellular therapy. ISBT Science Series 10 (S1):357-365.
5. Moll G & Ringdén O (2016) Cryopreserved or fresh mesenchymal stromal cells: only a matter of taste or key to unleash the full clinical potential of MSC therapy? Springer - Biobanking and Cryopreservation of Stem Cells 951:77-98.

Biography

During the past decade, Guido Moll has studied in collaboration with leading clinical stem cell and tissue engineering pioneers the immunomodulatory and regenerative properties of human multipotent mesenchymal stromal cells (MSCs) and other advanced therapy medicinal products (ATMPs) in a highly translational research environment at the Karolinska Institute in Stockholm, Sweden, the Berlin-Brandenburg Center/School for Regenerative Therapies (BCRT/BSRT) at the Charité Universitätsmedizin Berlin, Germany, and the Queensland Institute for Medical Research (QIMR) in Brisbane, Australia. The goal of Guido's research is to enhance the safety and efficacy of novel ATMPs in various therapeutic approaches.

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