

Review of clinical trials & biobanks that harness cell therapy for regenerative medicine

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ABSTRACT

Background: Recently private cord blood banks (CBB) have been diversifying their services beyond umbilical cord blood (UCB) and it is now possible to find umbilical cord tissue (UCT) or adipose tissue (AT) storage services in CBB around the world. These additional services store mesenchymal stem cells (MSC) that are valued due to their immunomodulatory and differentiation properties (among others). The aims of the present study are to review the business models of private biobanks and to separately identify trends in cell therapy clinical trials (registered between 2011-2015) that target orthopaedic and heart-related diagnoses.

Materials and Methods: The Parent's Guide to Cord Blood (PGCB) Foundation conducted a survey of all CBB worldwide between the summer of 2014 and spring of 2015. For each CBB identified, survey responses were obtained from their website, via email, and via phone calls. In addition, PGCB Foundation has collaborated with CellTrials.info to analyse all cell therapy clinical trials registered between 2011-2015 using the ClinicalTrials.gov and World Health Organization registries.

Results: Worldwide, PGCB Foundation identified a total of 214 private CBB, of which 107 also offer UCT storage and 18 also offer AT storage services.

The survey of clinical trials using cells to target orthopaedic and heart-related conditions revealed a sum of 15300 patients enrolled in a total 212 active clinical trials. Among these, 63.5% of patients were participating in 105 cell trials targeting heart-related conditions, while 36.5% were enrolled in one of the 107 cell trials targeting orthopaedic conditions.

The source of funding was academia for 121 of the trials, as opposed to 85 funded by industry, while the academia-industry partnership was marginal at 5 trials (1, unknown).

Autologous therapies comprised the majority of these trials (157 enrolling 75.1% patients), with most of the remainder classified as purely allogenic trials (48 for 23.9% patients), and trials that use both autologous and/or allogenic cells are marginal (3 for 0.7% patients) (4 trials unknown for 0.3% patients).

The source of the cells used in these trials was predominantly adult stem cells in 180 trials corresponding to 85.2% patients, versus the use of differentiated cells (17 trials for 8.8% patients), perinatal stem cells (13 trials for 5.0% patients) or even differentiated cells co-administered with stem cells (2 for 1.0% patients).

Conclusions: The present study reveals the current trends within orthopaedic and heart-related clinical trials that use cells as part of therapy. This dataset should be of interest to both professionals and also potential patients within these areas. This study reveals that autologous cell therapy is dominant for these indications, which opens a window for development of biobanking for future personalized medicine. Moreover, very few orthopaedic or cardiac cell trials use perinatal sources of stem

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cells. These results, together with the ongoing diversification of the CBB industry, might possibly lead to the development of perinatal cell therapies for some conditions with poor treatment success today. The potential market for some of these diagnoses is huge, for example

ischemic heart disease was responsible for 7.4 million deaths in 2012 according to the World Health Organization (WHO). Perhaps in the future the pharmaceutical industry will make a bigger investment in this field, which today is mostly funded by academia.