
Roundtable: Embryonic or adult stem cells: scientific and ethical considerations

The use of human embryonic stem cells in EU research projects

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The use of human embryonic stem cells (heSCs) in hazard assessments becomes crucial if no available *in vitro* model can detect the toxicological mechanisms under evaluation or if the extrapolation from animal cells or cells of a carcinogenic origin to the human situation is hampered due to species variations. Cardiomyocytes derived from heSCs may be advancing the current situation of pharmacological toxicity and safety assessments of the heart – a major purpose of the StReP: “InVtiroHeart”. Currently available *in vitro* cardiac assays are mainly based on primary animal cardiomyocytes or cell lines expressing human cardiac proteins as primary human cardiomyocytes are limited available. This is problematic as non-clinical cardiac toxicological and pharmacological evaluations are strongly hampered by interspecies variations such as heRG channel expression. One of the most frequently-cited limitations of *in vitro* tests for assessing health effects are deficiencies in the bi- otransformation of test chemicals. Major obstacles of using human primary hepatocyte cultures are their loss of metabolic competences in culture and their restricted accessibility. The StReP “Vitrocellomics” is aiming to use heSCs to establish stable cell lines and 3-dimensional *in vitro* models that reflect human hepatic properties. Finally, the area of reproductive/developmental toxicity is requesting scientific solutions for assessing adverse effects on spermatogenesis and embryogenesis. Using heSCs for these purposes are among the main objectives of the integrated projects “ReProtect” and “ESNATS”. EU research projects applying hESCs have to be in compliance with ethical framework set by the European Commission in FP6 and FP7 and by the Member-states in which the research is carried out. The use of hESCs moreover, requests the application of quality controls that are beyond those that have been laid down in the good cell culture practise guidelines.

Keywords: cardiotoxicity, metabolism, reproductive toxicity, interspecies variations, quality aspects of hESC