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News Release

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Stem cell study paves the way for patient therapies

Stem cells that have been specifically developed for use as clinical therapies are fit for use in patients, an independent study of their genetic make-up suggests.

The research – which focused on human embryonic stem cells – paves the way for clinical trials of cell therapies to treat conditions such as Parkinson’s disease, age-related degeneration of the eyes and spinal cord injury.

The study also sets out a cost-effective approach for monitoring the quality of stem cell-based products and newly emerging cell therapies.

Stem cells have the potential to become any of the varied cell types found in the body. Researchers have been investigating how they may be used to repair or replace damaged tissues in patients.

However, because the cells continuously produce copies of themselves, there are concerns that they may acquire genetic abnormalities that could lead to cancer.

Scientists at the University of Edinburgh investigated the genetic make-up of human stem cells that have been grown in the laboratory from cells found in the early embryo.

The 25 cell lines tested were all ‘clinical-grade’ – which means they meet the strict quality requirements for cell lines earmarked for use as therapies.

The team at the Medical Research Council Centre for Regenerative Medicine analysed each of the cell lines using a technique called molecular karyotyping, which is a highly sensitive method of detecting genetic abnormalities.

More than half of the cell lines carried large but stable genetic differences, the researchers found. However, these changes are also present in healthy people without significant consequences, reflecting the genetic diversity of the human population.

They found that a small number of the cell lines acquired genetic problems if they were grown in the laboratory for too long. Researchers say this highlights the need for continued genetic testing of emerging stem cell-based products to ensure they are suitable for use in patients.

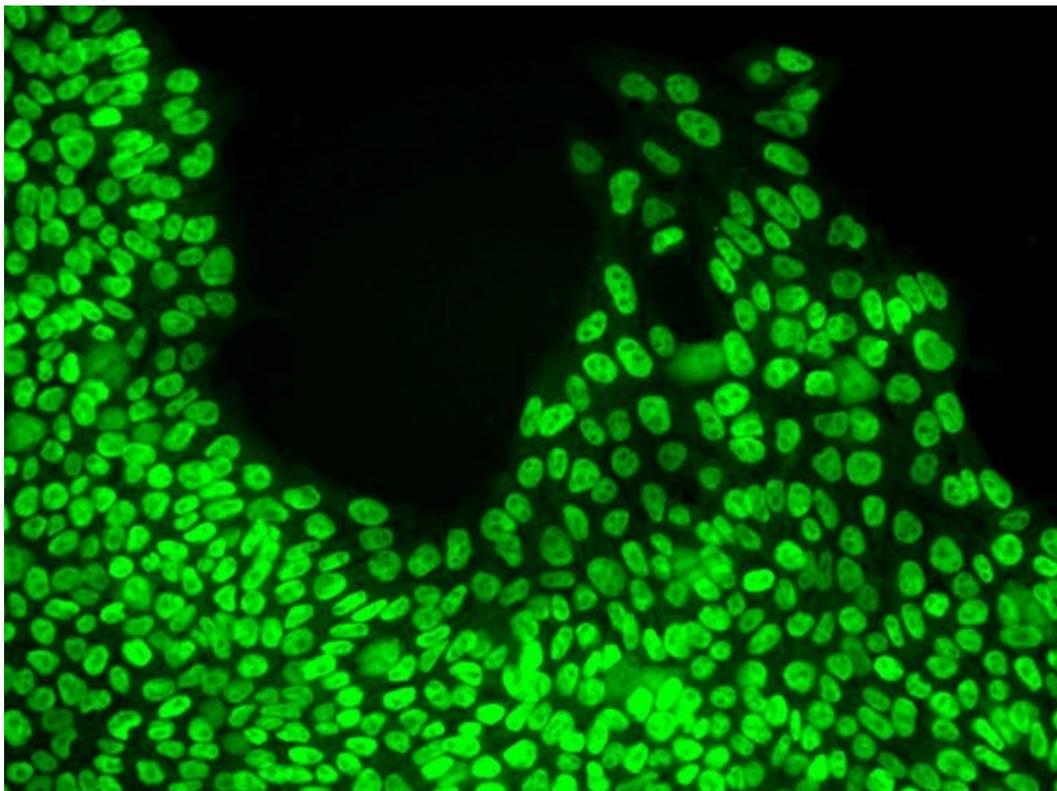
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The study is published in the journal *Scientific Reports*. It was funded by the Medical Research Council and The Cure Parkinson's Trust.

More than three-quarters of the global clinical-grade embryonic stem cell lines have been established in the UK. The stem cell lines analysed in the study were established for clinical use by the Universities of Sheffield and Manchester, King's College London, and Roslin Cells, a company that specialises in the production of clinical-grade cells for use in therapies.

Dr Tilo Kunath, Senior Research Fellow at the Medical Research Council Centre for Regenerative Medicine, University of Edinburgh, said: "This is the largest study of therapeutically useful stem cells to date and shows that we are in a good place to push forward new cell therapies into clinical trials."

Dr Paul Colville-Nash, Programme Manager for Stem Cell, Developmental Biology and Regenerative Medicine at the MRC, said: "Collating a library of stem cells that we understand and know are fit for use in patients is vitally important if these are to be routinely used in the clinic. This work complements that of the UK Regenerative Medicine Platform that is seeking to address the key knowledge gaps needed to accelerate development, and ensure the safety and efficacy, of emerging stem cell therapies."



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