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Results of clinical trial on the use of cell therapy for treating liver cirrhosis

Background

Chronic liver disease is commonly caused by excessive alcohol consumption, obesity and/or viral hepatitis. Even if these causes are removed or treated liver cirrhosis can still progress to liver failure. Liver cirrhosis is the long term damage of the liver resulting in a build-up of scarring and thickening that prevents it from working properly.

Although there have been advances in the understanding of the mechanisms associated with cirrhosis, liver transplantation is still the only treatment proven to cure the disease. With a shortage of donors and high medical costs it is important to investigate and develop alternative treatments.

Research looking into stem cell therapy to treat liver disease has shown promising results. However, the few studies that have researched this had small numbers of participants and short follow up periods.

The clinical trial

The National Institute for Health Research (NIHR) Birmingham Liver Biomedical Research Unit (BRU) coordinated the REALISTIC trial which is the first multi-centre, randomised controlled trial investigating the use of cell therapy to treat liver cirrhosis. The trial was a collaboration between the University of Birmingham, NHS hospitals (Birmingham, Edinburgh and Nottingham), the pharmaceutical industry (Chugai Pharmaceuticals CO., Ltd) and a charitable organisation (the Wellcome Trust).

This study looked at two cell treatments. The first treatment was a medication called granulocyte colony-stimulating factor (G-CSF) that helps to stimulate stem cells in the bone marrow to be released around the body. The G-CSF is manufactured by Chugai Pharmaceuticals and is administered as an injection. In addition to the G-CSF some of the participants received additional stem cell infusions, this involves the participant's own stem cells being filtered from their blood and then injected back into the body.

The clinical trial recruited 81 participants with liver cirrhosis. Participants were randomised into one of three groups: standard care, G-CSF or G-CSF and stem cell infusion. All participants completed at least one treatment day, five participants did not complete the full course of treatment. Effectiveness of the treatment was measured by change in seriousness of the disease 3 months after treatment.

Outcome

There were no improvements in liver function or fibrosis in the G-CSF or G-CSF with stem cell infusion groups compared to standard treatment.
Patients in the G-CSF with or without stem cell infusion groups experienced more side effects than those receiving standard treatment.

What does this mean?

The results of the trial found no benefit to the use of G-CSF with or without stem cell infusion for improving liver function and reducing scarring. Although the findings were not positive they are important for highlighting that more trials need to be conducted to further investigate the effectiveness of stem cell therapy for liver disease. The robust design of this trial can be used as a model for future trials and pave the way for research to investigate developing treatments for liver cirrhosis.

This summary/report presents independent research funded by the National Institute for Health Research (NIHR). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

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Further information on the NIHR Birmingham Liver BRU: www.birmingham.ac.uk/liver
Published manuscript: https://www.sciencedirect.com/science/article/pii/S2468125317303266

V1.0 27th November