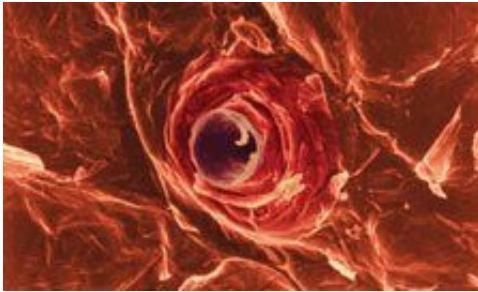


# New clinical trial to treat skin disorder begins

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Human epidermis under the microscope

A Phase II trial to treat skin erosions in patients suffering from the severe genetic skin disorder, Recessive Dystrophic Epidermolysis Bullosa (RDEB), begins today, led by a team of scientists and clinicians at King's Health Partners.

In RDEB patients the skin blisters at the slightest knock or rub, causing painful, open wounds which result in scarring and fusion of fingers. It is estimated that there are 5,000 people with EB in the UK.

The placebo controlled trial will involve 20 RDEB patients. It will be led by Professor John McGrath, Professor of Molecular Dermatology at King's College London and Honorary Consultant Dermatologist at Guy's and St Thomas' NHS Foundation Trust. The trial, which is scheduled for completion early in the autumn, is funded jointly by Intercytex, The Technology Strategy Board and the charity, DEBRA.

Professor McGrath's team will administer a single series of injections of the Intercytex therapy, ICX-RHY, or a placebo, around the margins of several selected skin erosions. Patients will then be assessed initially over a three month period to measure end points including time to wound closure, wound recurrence and erosion pain.

Professor McGrath has already used ICX-RHY successfully to treat 14 EB patients on a compassionate use basis. Commenting on the start of the trial, Professor McGrath said 'Finding out whether a new treatment can help people with EB heal their wounds faster makes this an important clinical trial. We plan to test cells called "fibroblasts" to see if injection into the skin affects wound healing. The trial represents a significant step forward in taking research from the laboratory to the clinic.'

Ben Merrett, CEO of DEBRA, added: 'Some forms of EB, like RDEB, can be very debilitating and there is a high unmet medical need for an effective treatment. Judging by the initial patient reaction to ICX-RHY, this could be an exciting step forward in treating the disease and make a significant, long-term difference to people who lead very difficult lives.'

ICX-RHY is a suspension of human dermal fibroblasts (HDFs, which are naturally derived skin cells) in cell storage medium, for injection into the skin. The newly introduced HDFs are thought to repair the extracellular matrix to improve skin structure and function.

Provided by King's College London

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