

Researcher (s):	Prof Liam Grover (PI) Co-Researchers: Prof Anthony Metcalfe, Prof Ian Chapple, Prof Adrian Heagerty
Research Institution:	University of Birmingham, UK
Project Title:	A novel spray delivery system for the treatment of mucosal scarring in epidermolysis bullosa
Research Area:	Wound Healing
Start Date: Sept 2020	End Date: Aug 2022
Funded by:	DEBRA Ireland and UK

Lay Summary

This project will work towards the development of a new spray delivery system as both a treatment and preventive strategy for scarring that affects the mucosa or membranes in the body which characterises EB, and the associated morbidity. The overall aim will be to formulate this delivery system so that it can be used to deliver three candidate anti-fibrotic molecules. Importantly, the final output of the project will be three systems formulated and manufactured in a way that would allow them to be used in a comparative clinical trial, which will be funded either commercially or through an additional grant application.

The overall objectives of this project will be to:

1. Formulate, with clinicians and patient groups, an oral spray that can be used for delivery into the buccal (cheek) cavity.
2. Absorb therapeutic antifibrotic molecules into this material and demonstrate their retained therapeutic potency during a period of storage and then spraying.
3. Develop a GMP (Good Manufacturing Practice) process for manufacture and filling of the drug containing materials.
4. Put in place the paperwork required for a phase I trial of the oral preparation.

All of the above objectives are achievable in a two-year project given that they have 1) undertaken the basic preparation of a spray-based gel technology, and 2) developed GMP processes to manufacture the material that we propose to use for spraying. Furthermore, they have already undertaken biocompatibility testing of the materials in-line with ISO 10993 (an industry standard for biological testing, risk

management and evaluation), and have performed human contact trials in intact skin. Both enabling the use of the preparations in the relatively short term.

Project Abstract

This project will work towards the development of a new spray delivery system as both a treatment and preventive strategy for the mucosal scarring that characterises EB, and the associated morbidity. The overall aim will be to formulate this delivery system so that it can be used to deliver three candidate anti-fibrotic molecules (decorin, E-resolvin, and dextran sulphate). Importantly, the final output of the project will be three systems formulated and manufactured in a way that would allow them to be used in a comparative clinical trial, which will be funded either commercially or through an additional grant application.

Blog post written about project for website

<https://debraireland.org/news-research/a-spray-to-treat-oral-scarring-in-eb/>

Quotes we have from researchers

‘We are really pleased to receive this DEBRA funding for our project. This will enable us to develop our spray delivery system which we believe can be of significant benefit to patients with Epidermolysis Bullosa.’ – Professor Liam Grover

‘We are very grateful to DEBRA for their support in funding the spray delivery system project. We hope that the outcomes of the project will advance the possibilities for delivery of therapeutic molecules into the mouth and improve the quality of life for patients with Epidermolysis Bullosa.’ – Professor Tony Metcalfe

Researcher (s) Bio

Liam Grover is a Professor in Biomaterials Science and the Director of the Healthcare Technologies Institute at the University of Birmingham UK. The Healthcare Technologies Institute brings together leading experts from a variety of disciplines across the University of Birmingham to advance new technologies and treatments that encourage better tissue healing and rehabilitation tools.

Tony Metcalfe is a Professor of Wound Healing at the University of Birmingham. Tony has worked in academia, industry and the not-for-profit sectors and his research focus includes tissue repair, translational medicine and scar free healing.

Iain Chapple is Professor of Periodontology and Head of the School of Dentistry at the University of Birmingham UK and Consultant in Restorative Dentistry. He leads a strong team as part of Birmingham’s Periodontal Research Group, and is Director of Research for the Institute of Clinical Sciences at the University of Birmingham. Iain

runs a national clinical oral and dental service for adult EB patients in close collaboration with Professor and Doctor Adrian Heagerty, a Consultant Dermatologist and EB expert.

Professor Adrian Heagerty is a Consultant Dermatologist at University Hospitals Birmingham NHS Trust and an Honorary Professor of Dermatology at the Institute of Inflammation and Ageing at the University of Birmingham. Prof. Heagerty is currently working on several research projects to improve the quality of life of people suffering from EB.