

CASE STUDY



HAWS; Haemoglobin Application to Wounds Study, a single-centre, controlled, prospective randomized trial in diabetic foot ulcer patients

A North East and North Cumbria Innovation Pathway Partnership Case Study

In early 2017 MedConNecT North introduced Infirmary Healthcare, UK distributor of Granulox® haemoglobin spray, to various Trusts in the North East & North Cumbria. After initial discussions, Cumbria Partnerships NHS Foundation Trust and InFirst entered an agreement to develop a clinical trial aimed at treatment of diabetic foot ulcers (DFU) with Granulox.

Within Cumbria Partnership, study development was led by Dr Stacey Fisher (GP with Special interest in Research) and Dr Leon Jonker (Science & Innovation Manager), with support from the wider research team and Trust's West Cumbria podiatry team.

DFUs are a common complication of diabetes and they have significant cost implications; managing them costs the NHS £650 million per year (NHS Diabetes report). The healing rate of DFUs is poor and on average only 24% of wounds will heal after twelve weeks of treatment (Margolis, 1999).

Furthermore, those with larger ulcers and co-morbidities respond poorly to standard treatment in the first four weeks – and they end up being at risk of long-term wounds with substantial loss of quality of life and potentially risk of amputation.

Granulox® is a novel spray containing purified haemoglobin for use on chronic wounds. This spray is an innovative class III medical device designed for the treatment of chronic wounds, such as venous leg ulcer, arterial leg ulcer, mixed leg ulcer, diabetic foot ulcers, burns, secondary healing of surgical wounds and pressure sores. Granulox® can also be used on sloughy and infected wounds.

Initial discussions were centred on the potential of Granulox® spray demonstrated in 2 randomised control trials in venous leg ulcers, multiple case series in wounds of mixed aetiology and retrospective studies to date, and how the NHS could help to design a prospective research trial in diabetic foot ulcer.

The aim was to plan a methodologically sound study that will provide further evidence on the effectiveness of Granulox® spray for accelerated DFU wound healing. These discussions culminated in the Haemoglobin Application to Wounds Study (HAWS).

This randomised trial is now ethics-approved and has enrolled its first patients; it assesses the effectiveness of the Granulox® spray at 12 weeks of treatment, compared to an equally large group of 20 patients who will receive standard of care treatment as usual.

The hypothesis is that improved healing rates will help to close more wounds faster, improve the patient's quality of life as well as decrease the burden on the NHS.

Although the HAWS study is led and delivered by Cumbria Partnership NHS staff, this was enabled by effective collaboration with Infirst Healthcare and MedConNecT North.

This alliance is a fantastic example of joint working between the NHS in the North East & North Cumbria and a Medical Technology Partner to provide a robust study for evidence generation involving a cutting edge device.