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New Study Shows Diabetic Foot Ulcers Treated with Granulox Demonstrated Significantly Better and More Rapid Wound Closure

- *UK's largest study to date in diabetic foot ulceration, unveils promising results for Granulox®*
- *One quarter of patients saw a 100% reduction in wound area after just four weeks treatment with Granulox®*[1]
- *Average wound reduction was 62.3%*[1]*and the median was 56%*

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5 August 2015 London – Innovative oxygen therapy, *Granulox®*, is hailed as an effective, safe and easy-to-use treatment, with the potential to revolutionise wound care, according to data presented at the recent European Wound Management Association (EWMA) conference, and published in the British Journal of Nursing.

The comprehensive study – the first of its kind in the UK – was conducted by South Tees NHS Hospitals Foundation Trust and treated 20 patients with non-healing diabetic foot ulcers that were present for 12 weeks or more, with *Granulox®*. After just four weeks, all trial patients reported a reduction in wound surface area, elimination of slough and an improvement in exudate levels.

A quarter of patients reported a 100% reduction in wound area. The average wound size reduction was 62.3%, and even wounds which had been present for 12 months or more reduced by an average of 24% within the four weeks.[1]

All patients with a previous wound bed slough between 10%-100% were slough-free, with no debridement required during the treatment with *Granulox®*. In addition, significant reduction in exudate levels across all patients: a 29% reduction in wounds with mild exudate (2 out of 7 patients), a 86% reduction in moderate exuding wounds (6 out of 7 patients) and a complete resolution (100%) of all six patients with severe exuding wounds. These results demonstrate the transformative impact of *Granulox®* in patients with previously non-healing wounds.[1]

Both the patient and clinician experience of *Granulox®* was positive, with the treatment's easy-to-use spray functionality hailed as a key product benefit. Sharon D. Bateman, study

author and specialist tissue viability nurse remarks: "Diabetic foot ulcers have a significant impact on a patient's quality of life and place patients at higher risk for lower limb amputations. The management of DFU patients can place a significant burden on NHS resources. Aside from the clinical benefits seen in the trial, 75% of patients were able to apply *Granulox®* independently, making the prospect of patients managing their DFU independently or with the help of their healthcare team a distinct reality."[1]

Manfred Scheske, CEO, infirst Healthcare comments: "As an area of huge unmet need, the latest data demonstrating that *Granulox®* promotes rapid and complete wound closure should revolutionise the way clinicians approach the management of foot ulcers in patients with diabetes. This latest trial adds to the evidence base for *Granulox®* as part of a gold standard wound-care regime."

Additional study details

The trial included 20 adult patients with diabetic foot ulcers located beneath the ankle – the most common anatomical site for DFUs to occur. Of the 20 patients in the study, 7 (35%) patients suffered from type 1 diabetes with the remaining 13 patients, (65%) with type 2 diabetes. Study participants were classified as scoring 2 on the Site, Ischemia, Neuropathy, Bacterial Infection, Area and Depth (SINBAD) scale, which assess the severity of foot ulcers and the risk factors that may inhibit healing. Patients with a SINBAD score of 3 or higher were excluded from the trial, alongside pregnant participants, patients suffering from infected ulcers or who were receiving antibiotic or corticosteroid therapy.[1]

-Ends-

Further Details:

- Case studies in diabetic foot ulcers and other chronic wounds are available on request
- Interviews available with Sharon D. Bateman, Nurse Practitioner, Specialist in Tissue Viability, South Tees NHS Hospitals Foundation Trust
- To arrange interviews, case studies and for all other media enquiries, please contact:
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About chronic DFUs

Diabetes affects 3.2 million people in the UK,[2] with 1 in 10 patients experiencing foot ulcers or lesions as a result of the condition.[3] DFUs are among the most common reasons for admission into a healthcare setting, with patients increasingly susceptible to infection, tissue damage, amputation and long-term disability. Chronic DFU costs the NHS approximately £661 million a year[4] and the financial burden of diabetes is expected to rise year-on-year in the UK. It has been estimated that 7,000 people will require amputations as a result of DFU in one year alone.[5]

About Granulox®

Granulox® was launched in the EU in 2012 and to the NHS in England, Wales and Scotland in 2014. Granulox® is an innovative, topical haemoglobin spray treatment for chronic wounds such as venous leg ulcers, arterial leg ulcers, mixed leg ulcers, diabetic foot ulcers, secondary healing of surgical wounds and pressure sores. The active haemoglobin improves the oxygen supply to chronic wounds by aiding diffusion of oxygen into the wound base, to accelerate rapid healing, even in previously non-healing wounds. The improved oxygen supply to the base of the wound has been shown to improve healing speed by 75% vs standard care alone,[6] with a statistically significant reduction in pain within the first 2 weeks of treatment, and 93% more chronic wounds closed within 6 months vs standard care[7,8]

About infirst Healthcare:

infirst Healthcare is a UK-based healthcare company which operates in the US and the UK. Its developments aim to build on the trust and safety of well-known drugs and to develop formulations which result in a genuinely perceived difference in performance. The ultimate goal is improved and highly effective health management at an early intervention stage, involving patients, the family practitioners and paediatricians as well as pharmacists.

References

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