

Inotec AMD awarded £1m contract from NHS England to tackle hard to heal wounds and diabetic foot ulcers



Inotec AMD has been awarded a further Small Business Research Initiative for Healthcare (SBRI Healthcare) development contract to facilitate the commercialisation of its wound healing technology. This award follows directly on from the Phase 1 contract, which supported a successful initial study of the company's patented NATROX™ Topical Oxygen System for the treatment of difficult to heal foot ulcers commonly suffered by diabetics.

This second study will involve up to 140 patients in a randomised, placebo controlled, double blind, multicentre trial to investigate the effect of Topical Oxygen Therapy on the reduction in wound size, when compared to standard treatment. There will also be a further study looking at patients who have had ulcers for over 6 months.

Consultant vascular surgeon, Dr Paul Hayes, who was involved in the first pilot study says "diabetes, now affects over 2.8 million people in the UK and around 340 million people worldwide. Foot ulcers are a serious and increasingly common complication of diabetes and are most often the result of nerve damage or poor circulation associated with the disease. These ulcers can lead to amputation if left untreated and existing treatments usually have little or no effect with over 30% of these wounds taking more than two years to heal, and many never heal at all".

Oxygen is a key requirement for all cellular processes, and is particularly important in wound healing. There has been a longstanding interest in providing additional oxygen to healing wounds. The NATROX™ system is designed to overcome a number of problems associated with previous methods of oxygen therapy by delivering continuous oxygen 24 hours a day to the wound bed through a range of specifically designed dressings. Importantly the patient remains ambulatory.

In the Phase 1 study, Addenbrookes Hospital in Cambridge and St Georges Hospital in London jointly carried out a 6-month case study involving 10 patients with chronic diabetic foot ulcers who were studied using NATROX™ for a period of 8 weeks each. Seven of the ten wounds showed healing trajectories evidenced by the decreasing area of the wound. Even when the non-responding wounds were included, the average decrease in wound area obtained by a regression analysis was 4.9% per week.

The device was very well received by both clinicians and patients, with patients giving it a median acceptability score of 9.9/10 for day use and 10/10 for night. There was also a trend towards improved pain scores within the small cohort, which fell by almost a quarter over the course of the study.