

Title: Prospective, multicentre, randomised controlled feasibility trial of the application of NATROX® topical oxygen therapy in patients with chronic and delayed healing foot ulcers.

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Study details: described in ANODE Protocol v5.1 dd14Jan2022

Summary

The ANODE study was conducted in two NHS Trusts, namely South Tyneside & Sunderland and North Cumbria Integrated Care and coincided to a large extent with the peak of the COVID19 pandemic. Despite having screened a lot of patients, particularly in North Cumbria, not many patients were willing to participate in the study (in North Cumbria 38 eligible patients declined whereas 21 consented to take part). Of the total 30 enrolled patients who entered the four-week screening phase, only 14 (8x control and 6x Natrox) entered the twelve-week trial phase. There is insufficient data to comment on the efficacy of NATrox in relation to wound healing. Withdrawals from the trial phase study (two in control arm) and challenges seeing patients in person due to COVID19 restrictions further affect the data quality for the study. Taken together, the planned 24 patients were recruited into the ANODE study. However, poor record keeping, COVID19 restrictions and low uptake by patients meant that definitive conclusions cannot be drawn on the potential of Natrox as an adjunct treatment for diabetic foot ulcers.

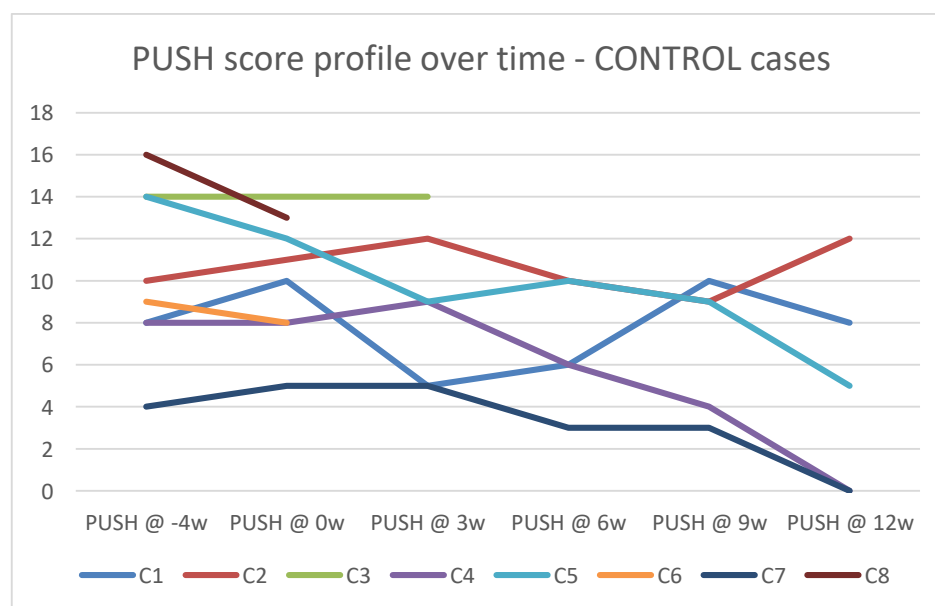
Table 1, Demographics

Issue: South Tyneside did not collect a number of basic baseline measures (i.e. none or almost none of variables like patient age and sex, and one data point for chronicity of the wound).

	All participants (including screening phase), n=30	Control arm, n=8	Natrox arm, n=6
Patient sex, m/f/not known (n)	10/12/8	1/3/4	1/3/2
Patient age, mean in years	62 (n=21)	67 (n= 4)	69 (n=3)
Wound chronicity*, median in weeks	7 (n=29)	7	17

*If patient or podiatrist entered eg 6+ weeks, then 6 weeks was recorded.

Figure 1. Wound sizes as measured with PUSH score.



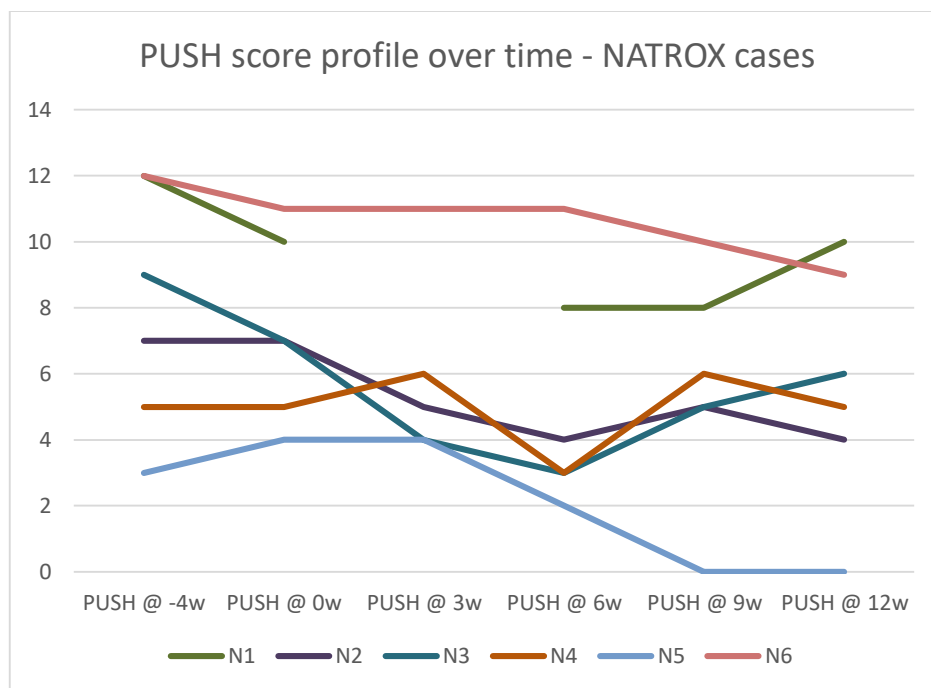


Figure 2. Overview of ANODE study in both South Tyneside and North Cumbria (NCIC)

