Long Term Outcomes of a Randomized Controlled Trial with Negatively Charged Microspheres (NCM*) Technology Compared to Control

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Background: Non-healing wounds are a growing clinical problem and a major burden on patients and health care systems. We report the results of an extended long term follow up of a RCT study of treatment of recalcitrant ulcers with Negatively Charged Microspheres (NCM*) Technology vs. control treatment (saline soaks).

Aim: To evaluate the long term condition, safety and burden on patients and health systems following treatment of chronic and hard to heal wounds with NCM technology compared to control.

Methods: After completion of the RCT active phase of 4 weeks treatment with NCM or control (saline soaks), patients were eligible to continue to the extended 2 year follow-up study. During this period patients were treated according to each investigator’s choice of standard practice, excluding NCM or saline soaks. The follow up study included assessments of wound status, incidence of adverse events and number of unplanned hospitalizations.

Results: Forty-seven patients continued to the long term follow-up phase, 27 in the NCM group and 20 in the control group. 41 patients completed the two year extended follow-up. The incidence of adverse events reported in the NCM treated group was lower than in the control group (14.8% vs. 30% respectively). There were 50% more wounds that remained closed in the NCM group compared to the control group. There was a statistically significant reduction of unplanned hospitalizations and hospitalizations duration in the NCM vs. control group (mean change of -1.15 hospitalizations events per patient vs. +0.64 respectively p= 0.0038; mean change in number of hospitalization days per patient -25.0 days vs. +0.91 respectively p=0.0095).

Discussion: NCM treatment lead to a significant reduction in hospitalization burden. This significant reduction is further highlighted by the fact that the NCM group had greater hospitalization burdens before beginning NCM treatment. An interesting finding is the reversal of the natural course of the disease: in the control group there is, as expected, an increased hospitalization burden with time (patients become older and sicker) whereas in the NCM group the hospitalization burden is significantly reduced compared to their basic condition.

Conclusions: NCM has shown long-term safety as well as a potential reduction in wound care and hospitalization burdens. These outcomes may suggest an important clinical and cost-effective role for NCM in chronic wound care.

RCT Long-Term Follow Up

6 months, 12 months and 24 months visits; standard treatment (not saline or NCM)

DB Active Phase

FU phase

Extended 2 years FU phase

Randomization / Baseline

NCM

Treatment per investigator

Saline

Treatment per investigator

Weeks 1 2 3 4 6 8 10 13 26 52 104

*NCM is PolyHeal™ by MediWound Ltd

This work has been made possible by funding from MediWound Ltd

Baseline 3 Weeks 11 Weeks 24 Months

83 yr old male with a traumatic leg ulcer and wound infection. Wound duration = 6 weeks, size = 24.8cm². NCM out-patient daily application for 3 weeks ending in clean granulation tissue that could be grafted. Good wound closure by graft seen at week 11 and closure maintained for 2 years

Baseline 4 Weeks 12 Weeks 19 Months

60 yr old female with a diabetic foot ulcer. Wound duration = 18 months, size = 19.5cm². NCM out-patient daily application for 4 weeks ending in clean granulation tissue that could be grafted. Wound was not grafted, but rather was treated towards secondary closure (12 weeks). The wound closed and remained closed after 19 months.