MONOCHROMATIC PHOTOTHERAPY IN PATIENTS WITH CHRONIC PRESSURE ULCERS

O Dehlin (1), S Elmståhl (1), F Gottrup (2); University Hospital, Malmö, Sweden (1), Bispebjerg UniversityHospital, Copenhagen, Denmark (2).

Meta-analysis of the efficacy of monochromatic phototherapy vs placebo phototherapy in elderly patients with grade II chronic pressure ulcers as evaluated in studies BL-030 and BL-034.

HYPOTHESIS

That treatment of chronic pressure ulcers in geriatric patients with Biolight® in comparison to placebo light, should result in shorter time until total pressure ulcer healing and a greater reduction in pressure ulcer area, defined as ulcer size during foll-low-up relative ulcer size at baseline.

OBJECTIVES

To perform a meta-analysis on the efficacy of monochromatic phototherapy (Biolight®) for up to 12 weeks on Grade II chronic pressure ulcers compared to placebo phototherapy as evaluated in studies BL-030 and BL-034. In addition, demographic data will be summarised and inspected for balance between treatment groups.

MATERIAL

The studies were performed at 9 centres in Sweden and Denmark. A total of 163 included patients; 79 in the phototherapy group (Biolight®), mean age 84 years, mean BMI 20.3, and 84 patients in the placebo group, mean age 84 years, mean BMI 21.5. Males or females aged 65 or more with Grade II chronic pressure ulcers according to Shea score localised either on the trunk or the foot, not having unstable diabetes mellitus, or previously diagnosed serious or terminal malignancy was included in the study.

METHODS

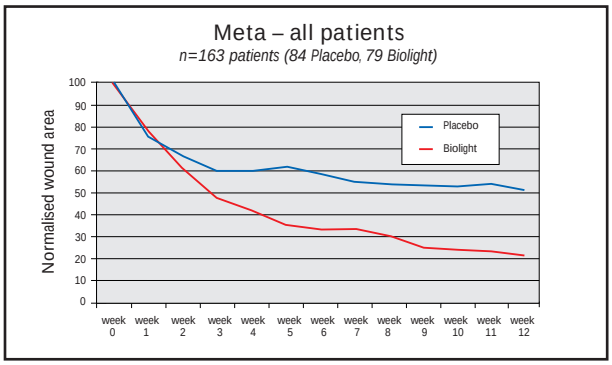
The studies BL-030 and BL-034 were randomised, placebo-controlled, multi-centre studies with parallel groups and a double-blind design.
Monochromatic infrared light at 956 nm and red light at 637 nm with light power 55.3 W/m^2 and total amount of energy 1.5 J/cm^2 was used.
Ulcer size was determined with a planimetric method and the overall mean was 4.4cm^2; photo was also taken. Treatment (Biolight® or placebo) was given according to a fixed scheme, from 5 to 2 times a week. All patients also received state-of-the art conventional treatment of their ulcers.

STATISTICAL METHODS

The primary efficacy variable, normalised reduction in pressure ulcer size, was calculated as the percentage change in ulcer size from baseline to week 12 using the Last-Value-Carried-Forward technique (LVCF) for missing values.

RESULTS

For the 163 included patients the mean normalised reduction in pressure ulcer size at week 12 was 0.79 for Biolight® and 0.50 for placebo (p=0.04).



The weekly reduction rate was 15.1% for patients treated with Biolight® and 10.9% for patients treated with placebo (ns).
An analysis of reduction in normalised ulcer size over time showed a larger non-significant area decrease in the Biolight® group (ns), see figure above.

Subgroup analysis.

For patients with any type of cardiovascular events (n=123) the mean normalised reduction in pressure ulcer size at week 12 was 0.76 and 0.44 for Biolight® treated and placebo treated patients, respectively (p=0.04).

For patients where pressure ulcer area measured at baseline was less than 1/3 of overall mean (n=31), the mean normalised reduction in pressure ulcer size at week 12 was 0.92 and 0.02 for Biolight® treated and placebo treated patients, respectively (p=0.01).

CONCLUSION

For both the primary efficacy variable, normalised reduction in pressure ulcer size from baseline to week 12 and the chosen subgroups of patient (patients with any type of cardiovascular events, and patient with pressure ulcer area measured at baseline less than 1/3 of the overall mean) the results show a significant different between -Biolight®- and placebo.

Therefore the conclusion is that -Biolight®- is superior to placebo in terms of reducing pressure ulcer size

Sponsored by:
Biolight