

# EFFECTIVENESS OF LAWSONIA INERMIS (HENNA) FOR THE MANAGEMENT OF PALMAR-PLANTAR ERYTHRODYSESTHESIA: PRELIMINARY RESULTS FROM A RANDOMISED CONTROLLED TRIAL

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## INTRODUCTION

Palmar-plantar erythrodysesthesia-PPE is a skin toxicity that has a common association with drugs such as liposomal doxorubicin and fluorouracil. PPE is not life threatening but can be very debilitating and impair patients' quality of life. The management for PPE includes treatment interruption, lengthening the interval between drug administrations, or dose reduction of the cytotoxic agent.

## OBJECTIVES

To test the effectiveness of a henna treatment protocol in the management of capecitabine and/or pegylated liposomal doxorubicin induced palmar-plantar erythrodysesthesia.

## METHODS

This is a randomized double-blind, placebo-controlled study (NCT01751893) with 80 patients assigned either to treatment (n=40) or control group (n=40). Outcome measures include PPE grade, EORTC QLQ-C30, HFS-14 and ECOG at pre (T0) and post (T1:3 weeks, T2:4 weeks, T3:5weeks) intervention. The treatment includes the application of henna (in the form of paste) to the affected areas (feet or/hands) twice a week.



## RESULTS

The GEE model showed a significant interaction between the treatment group and patients' PPE Grade across the 3 weekly measurements (Wald  $\chi^2(2) = 15.21$ ,  $p=0,001$ ).



Significant differences of mean were found in the PPE Grade between T0 and T1, T2 and T3 in the two groups (mean PPE was  $1.24 \pm 0.4$ ,  $1.25 \pm 0.7$ ,  $1.05 \pm 0.5$ ,  $1.00 \pm 0.6$  in the henna group versus  $1.25 \pm 0.6$ ,  $1.30 \pm 0.8$ ,  $2.15 \pm 0.9$ ,  $2.20 \pm 0.7$ ). The mean HFS-14 score was significantly higher in patients in the control group compared to those in the intervention group (higher score indicates greater QoL impairment). In the EORTC QLQ-C30, there was a statistically significant difference between T0 measurement and T3 ( $p < 0.001$ ). Statistical significant differences were not found in terms of the ECOG performance status.

## CONCLUSIONS

The preliminary findings showed that the lawsonia inermis was more effective to reduce the PPE grade compared to the placebo in this group of patients.



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