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Patients and methods

Here we report the results of a randomised, controlled clinical trial that compared the pain relieving efficacy, tolerability, and safety of 5% lidocaine medicated plaster to pregabalin in patients with post-herpetic neuralgia (PHN) or diabetic polyneuropathy (DPN).

The trial was planned and conducted using an adaptive design with one planned interim analysis of the data collected from the first 150 patients. The aim of this trial was to show non-inferiority of 5% lidocaine medicated plaster to pregabalin.

The primary efficacy endpoint was a 1-point reduction from baseline in NRS for an average score of ≥3 days to 2 weeks, as a measure of improvement in the level of pain experienced by patients. The primary efficacy endpoint was defined as the final score of the combined phase (Figure 5A) of the trial.

Efficacy endpoints

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Safety

In the safety analysis, all 281 patients (5% lidocaine medicated plaster or pregabalin) who received at least one dose of study medication were included in the safety analysis (i.e., primary analysis set).

Results

Percentage of patients with ≥30% reductions in NRS score at endpoint

Summary and conclusions

The results of this randomised, controlled trial of patients with PHN and DPN indicate that topical treatment with 5% lidocaine medicated plaster is generally well tolerated, effective, and safe due to a local anaesthetic effect and good patient compliance.

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References

