

# Efficacy and safety of diclofenac diethylamine 1.16% gel in acute neck pain: a randomised, double-blind, placebo-controlled study

Predel HG, et al. *BMC Musculoskelet Dis* 2013;14:250.

**Background/aim:** Neck pain (NP) is a common cause of discomfort presenting in primary care. Non-steroidal anti-inflammatory drugs are often used to alleviate NP, reduce associated inflammation and facilitate faster recovery. Topical diclofenac diethylamine (DDEA) 1.16% gel is well tolerated and proven to be clinically efficacious in acute and chronic musculoskeletal pain. This study assesses DDEA 1.16% gel compared with placebo gel in acute NP.

**Methods:** This was a randomised, double-blind, placebo-controlled study on patients with acute NP (n=72) treated with 2 g of DDEA 1.16% gel or placebo gel four times per day for 5 days. Study visits occurred on Day 1 (baseline and 1 hour [h] after first application of gel), Day 2 (24 h ± 4 h), Day 3 (48 h ± 4 h) and Day 5 (96 h ± 24 h; study end).

Efficacy assessments were carried out at each visit and included pain at rest (PAR), functional neck disability index (NDI) and pain on movement (POM) using a 100-mm visual analogue scale (no pain [0] to extreme pain [100]). Response to treatment was determined by a decrease in POM of 50% after 48 h. Monitoring for adverse events (AEs) was carried out throughout the study.

**Results:** For the primary outcome, there was a statistically significant ( $p < 0.0001$ ) decrease in POM at 48 h with DDEA 1.16% gel (19.5 mm) compared with placebo (56.9 mm). The decrease from baseline in POM with DDEA 1.16% gel was clinically relevant and nearly three-times lower than placebo (75% compared with 23%, respectively).

In terms of secondary outcomes, all POM scores were significantly lower from 1 h with DDEA 1.16% gel vs placebo (all  $p < 0.0001$ ). PAR and NDI scores were significantly lower from first assessment (24 h) onward with DDEA 1.16% gel vs placebo (all  $p < 0.0001$ ). With DDEA 1.16% gel (94.4%) vs placebo (8.3%) response to treatment was significantly higher ( $p < 0.0001$ ). There were no AEs with DDEA 1.16% gel.

**Conclusions:** DDEA 1.16% gel was effective and well tolerated in the treatment of acute neck pain. Assessment tools used to determine efficacy suggest that DDEA 1.16% gel rapidly reduced acute NP.

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