Efficacy and safety of a fixed combination of intramuscular diclofenac 75 mg + thiocolchicoside 4 mg in the treatment of acute low back pain: a phase III, randomized, double blind, controlled trial

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Sproviero E., Albamonte E., Costantino C., Giossi A., **Mancuso M.,** Rigamonti A., Tornari P., Caggiano G.

Author information

1 ASL Potenza, Hospital of Lauria, Lauria, Potenza, Italy - esmercure@tiscali.it.
2 ASP Potenza, Lauria, Potenza, Italy.
3 University Hospital of Parma, Parma, Italy.
4 Agenzia di Tutela della Salute (ATS) dell'Insubria, Porlezza, Como, Italy.
5 Agenzia di Tutela della Salute (ATS) dell'Insubria, Como, Italy.
6 Agenzia di Tutela della Salute (ATS) dell'Insubria, Alzate Brianza, Como, Italy.
7 ASL Potenza, Episcopia, Potenza, Italy.

Abstract

BACKGROUND: The management of acute low back pain (LBP) is directed to obtain early and maximum relief of the local and regional pain, and to improve mobility and physical function.

AIM: To evaluate the effects of a 4 mL-volume diclofenac 75mg/thiocolchicoside 4mg fixed dose combination (FDC) for intramuscular (IM) injection (test) compared to the separate injection of the two components (reference).

DESIGN: Phase III, randomized, controlled, double-blind (blind-observer), parallel-group.

SETTING: Twenty-two General Practitioners in Italy.

POPULATION: Adult outpatients with acute moderate-severe LBP at rest (≥50 mm at VAS) and stable muscle contracture (increase <5 cm in the distance between the two fingers of the examiner in the Schober test).

METHODS: Eligible patients were randomized to the test (N.=111) or reference (N.=112) treatment, both given IM once daily for 5 days. The primary efficacy endpoint of the study was the change from baseline in pain VAS score (0-100 mm) measured at rest 96±2 hours (day 5) from the start of treatment, one hour after the last injection.

RESULTS: Pain VAS Score markedly improved in both groups and the test was non-inferior to the reference in primary endpoint, i.e. the upper bound of the 95% confidence interval of the adjusted difference was lower than the pre-specified limit of 4 mm. There were no statistically significant differences between groups for improvements of pain measured at all time points before and one hour after injection, time to resolution of pain, improvements from baseline of

muscle contracture, and time to first resolution of muscle contracture. Approximately 20% of patients in the two groups used rescue paracetamol for pain relief. Both the test and the reference treatment were well tolerated in terms of adverse effects, laboratory parameters and vital signs.

CONCLUSIONS: A 5-day treatment with IM diclofenac+thiocolchicoside FDC in a 4-mL volume was as effective and well tolerated as the separate injection of the two components in improving pain symptoms in patients with acute moderate-severe LBP.

CLINICAL REHABILITATION IMPACT: The new diclofenac+thiocolchicoside FDC formulation may allow treating effectively acute LBP while reducing the number of injections and hence the risk of local adverse reactions, and improving the patient's compliance.