

IC01/04/DkP

Multicentre clinical trial to evaluate the analgesic efficacy and safety of Dexketoprofen (50 mg iv single dose, followed by oral dose of 25 mg t.i.d.) vs. Metamizol (2 g iv single dose, and 575 mg t.i.d oral) for the treatment of pain subsequent to ambulatory surgery

This study has been completed. Results will be soon available in the "Results section"

Sponsor: Laboratorios Menarini SA

Intervention: Dexketoprofen 50 mg. followed by Dexketoprofen 25 mg t.i.d. oral dose vs. Metamizol (2 g iv and then 575 mg t.i.d. oral) for the treatment of pain subsequent to ambulatory surgery

Condition: Postoperative pain

This study is designed to evaluate the analgesic effect of Dexketoprofen trometamol (50 mg iv single dose) vs. Metamizol (2 g iv single dose) in the early postoperative period (first 4 hours after iv dose) in patients after ambulatory surgery, assessing the pain intensity through visual analogue and verbal categorical scales

Study type & design: double blind, active controlled, parallel group study

Main criteria for inclusion:

Patients with postoperative pain after major ambulatory surgery (unilateral inguinal herniorrhaphy with mesh) Age 18-65 yrs Grade I or II ASA physical status (Assessment Scale of the American Society of Anaesthesiologists)

Main criteria for exclusion:

Chronic treatment with opiates and/or NSAIDs Presence of systemic infection or local infection on the surgical site before surgery. Patients with a history of peptic ulcer, gastric disease due to NSAIDs or gastrointestinal bleeding