

Additional file 6: Trials of oral dexketoprofen in arthritis

Reference	Methods	Details	Dosing regimen	Outcome measures	Efficacy results	Remedication, exclusions, and adverse events	Safety results	Quality score
Beltrán et al. Comparison of dexketoprofen trometamol and ketoprofen in the treatment of osteoarthritis of the knee. J Clin Pharmacol 1998; 38 (12 Suppl):74S-80S.	RCT, DB, 3 daily oral doses over 3 wks, parallel groups, 7-15 day analgesic washout	OA knee N= 183	Dexketoprofen trometamol 25mg TID N= 89	Pain intensity 100mm VAS  Lequesne index (functional ability)	Dexketoprofen trometamol 25mg TID Pain intensity (baseline) 63.9 + 22.6 Pain intensity (wk 1) 38.6 + 25.4 Pain intensity (wk 3) 32.1 + 25.6 Lequesne index (wk 1) 8.5 (6-11) Lequesne index (wk 3) 7 (5-10) Physician overall (wk 3) 73.2% better/much better Patient overall (wk 3) 67.1% better/much better	Remedication permitted, LOCF used where patients discontinued early  3 patients were excluded from analyses, 2 (1 per group) were lost to follow up and 1 patient in the dexketoprofen group did not take medication	Dexketoprofen trometamol 25mg TID No with >1 AE 27 All cause withdrawals 6 AE withdrawals 5	R 2 DB 2 WD 1  Total = 5
	Assessed pre-washout, at baseline and at weekly intervals  OA knee pain of at least 3 month's duration, regular NSAID use, Lequesne severity index of 5 to 13, and a Kellgren and Lawrence radiologic grade of 2-4, no mention of baseline pain intensity but baseline demographics indicate it was severe	11 centres in Spain  Ketoprofen 50mg TID N= 94	Patient overall assessment of symptoms (much worse, worse, a little worse, same, a little better, better, much better)  Physician overall assessment of symptoms (much worse, worse, a little worse, same, a little better, better, much better)	Significant reduction in pain at three weeks for dexketoprofen over ketoprofen	Ketoprofen 50mg TID Pain intensity (baseline) 63.2 + 20.9 Pain intensity (wk 1) 40.2 + 25.6 Pain intensity (wk 3) 40.5 + 28.2 Lequesne index (wk 1) 8 (6-10) Lequesne index (wk 3) 8 (6.5-11) Physician overall (wk 3) 50% better/much better Patient overall (wk 3) 45.5% better/much better	A total of 65 patients reported 101 adverse events, there were no significant differences between groups, and the majority of events were mild or moderate in severity, no serious adverse events were reported	Ketoprofen 50mg TID No with >1 AE 38 All cause withdrawals 11 AE withdrawals 7	OPVS = 13/16
Marengo et al. A multicentre, randomised, double-blind study to compare the efficacy and tolerability of dexketoprofen trometamol vs diclofenac in the symptomatic treatment of knee osteoarthritis. Clin Drug Invest 2000; 19: 247-256.	RCT, DB, 3 daily oral doses over 2 wks, parallel groups, 7-14 day analgesic washout	OA knee N= 117	Dexketoprofen trometamol 25mg TID N= 63	Pain intensity 100mm VAS  Pain intensity 4-pt VRS (no pain, mild, moderate, severe) - 1st wk only  Lequesne index (functional ability)	Dexketoprofen trometamol 25mg TID Pain intensity (baseline) 61.7 + 18.5 Pain intensity (wk 1) 45.4 + 24.9 Pain intensity (wk 2) 34.7 + 22.3 Lequesne index (wk 1) 9 (6-11) Lequesne index (wk 2) 8 (6-10) Physician overall (wk 2) 31.2% little better Patient overall (wk 2) 36.1% little better	Remedication permitted, LOCF used where patients discontinued early  2 patients were excluded from the ITT analysis as they were lost to follow-up	Dexketoprofen trometamol 25mg TID No with >1 AE 19 All cause withdrawals 9 AE withdrawals 6	R 2 DB 2 WD 1  Total = 5
	Assessed pre-washout, at baseline and at weekly intervals  OA knee pain of at least 3 month's duration, regular NSAID use, Lequesne severity index of 5 to 13, and a Kellgren and Lawrence radiologic grade of 2-4, persistent pain during washout period	8 centres in Spain  Diclofenac 50mg TID N= 54	Patient overall assessment of symptoms (much worse, worse, a little worse, same, a little better, better, much better)  Physician overall assessment of symptoms (much worse, worse, a little worse, same, a little better, better, much better)	No significant difference between treatments	Diclofenac 50mg TID Pain intensity (baseline) 62.1 + 22.8 Pain intensity (wk 1) 43.3 + 22.9 Pain intensity (wk 2) 40.6 + 22.2 Lequesne index (wk 1) 8.5 (7-11.5) Lequesne index (wk 2) 8.5 (6-10.5) Physician overall (wk 2) 27.8% little better Patient overall (wk 2) 25.9% little better	A total of 37 patients reported 63 adverse events, there were no significant differences between groups, and the majority of events were mild or moderate in severity, no serious adverse events were reported	Diclofenac 50mg TID No with >1 AE 18 All cause withdrawals 9 AE withdrawals 6	OPVS = 13/16

Abbreviations: RCT = randomised controlled trial; R = randomised; DB = double blind; wD = withdrawal or dropout; OPVS = Oxford Pain validity Score; LOCF = last observation carried forward; ITT = intention to treat; N = number; LA = local anaesthetic; VAS = visual analogue scale; VRS = verbal rating scale; AE = adverse event; SPID = summed pain intensity difference; TOTPAR = total pain relief