

Randomised population (n = 3,036)

Lumiracoxib 100 mg o.d. (n = 757) Lumiracoxib 100 mg b.i.d. (n=1,520)

Celecoxib 200 mg o.d. (n = 759)

Did not receive study drug (n = 2)

Did not receive study drug (n = 1)

Did not receive study drug (n = 1)

ITT/safety population (n = 755)

ITT/safety population (n = 1519)

ITT/safety population (n = 758)

Discontinuations (n = 402; 53.1%)

Administrative problems n = 102 (13.5%)
Due to protocol amendment[†] n = 90 (11.9%)
Unsatisfactory therapeutic effect n = 97 (12.8%)
Adverse events n = 96 (12.7%)
Withdrew consent n = 78 (10.3%)
 Due to adverse publicity[†] n = 25 (3.3%)
Protocol violation n = 10 (1.3%)
Lost to follow-up n = 9 (1.2%)
Abnormal laboratory value or test result n = 8 (1.1%)

Discontinuations (n = 792; 52.1%)

Administrative problems n = 226 (14.9%)
Due to protocol amendment[†] n = 199 (13.1%)
Unsatisfactory therapeutic effect n = 158 (10.4%)
Adverse events n = 187 (12.3%)
Withdrew consent n = 170 (11.2%)
 Due to adverse publicity[†] n = 68 (4.5%)
Protocol violation n = 22 (1.4%)
Lost to follow-up n = 7 (0.5%)
Abnormal laboratory value or test result n = 16 (1.1%)
No longer required treatment n = 3 (0.2%)

Discontinuations (n = 415; 54.7%)

Administrative problems n = 119 (15.7%)
Due to protocol amendment[†] n = 103 (13.6%)
Unsatisfactory therapeutic effect n = 88 (11.6%)
Adverse events n = 89 (11.7%)
Withdrew consent n = 93 (12.3%)
 Due to adverse publicity[†] n = 27 (3.6%)
Protocol violation n = 10 (1.3%)
Lost to follow-up n = 8 (1.1%)
Abnormal laboratory value or test result n = 5 (0.7%)
No longer required treatment n = 2 (0.3%)

Completed (n = 355; 46.9%)

Completed (n = 728; 47.9%)

Completed (n = 344; 45.3%)