**Table E7. Data abstraction of randomized controlled trials of SMRs**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Author, Year** | **Country Number of Centers and Setting** | **Inclusion Criteria** | **Number Randomized, Analyzed Attrition** | **Intervention** | **Study Participants** | **Duration of Pain (acute, subacute, chronic)** | **Duration of****Followup** |
| Pareek, 2009 | IndiaMulticenter | Age 18-70 with acutelow back pain and VAS score ≥6 at baseline (scale 0-10)Excluded: sciatica or other underlying spinal disorder, malignancy, osteoporosis | Randomized: 197Analyzed: 185Attrition: 6% (12/197) | A. Tizanidine 2 mg +aceclofenac 100 mg bid for 7 days (n=101) B. Aceclofenac 100 mg bid for 7 days (n=96) | A vs. BMean age 62 vs. 58 years39% vs. 40% femaleRace not reportedBaseline pain, function not reported | Acute/subacute; meanduration not reported but inclusion criteriarequired <30 days pain | 7 days |
| Ralph, 2008 | United StatesMulticenter | Age 18-65 years withmoderate to severe acute low back pain ≤3 daysExcluded: duration >3 days, sciatica, history of spinal pathology, neurologic symptoms, chronic low back pain, osteoporosis | Randomized: 562Analyzed: 547 for efficacy, 561 for safetyAttrition: efficacy3% (15/547); safety 0.2% (1/561) | A. Carisoprodol 250mg QID for 7 days(n=277)B. Placebo QID for 7 days (n=285 | A vs. BMean age 39 vs. 42 years49% vs. 55% female Race: 74% vs. 77% Caucasian; 15% vs. 12% African; 10% vs. 10% Asian;0.7% vs. 0.4% Native American; 0.4% vs. 0.4% other Baseline pain severity: mild0.4% vs. 0.4%; moderate 74% vs. 74%; severe 25% vs. 26% Baseline RDQ 10 vs. 10 | Acute; mean duration 2vs. 2 days | 7 days |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Author, Year** | **Results** | **Adverse Events Including****Withdrawals** | **Funding Source** | **Quality****Rating** |
| Pareek, 2009 | A vs. BPain at rest, mean change from baseline day 3: -3.01 vs. -1.90, p=0.0001;day 7 -5.88 vs. -4.35, p=0.0001Pain with movement, mean change from baseline day 3: -2.94 vs. -1.81, p=0.0001; day 7 -6.09 vs. -3.98, p=0.0001Global improvement, proportion of patients reporting good or excellent response: 75% (71/94) vs. 34% (31/94); RR 1.28 (95% CI 1.07 to 1.52) | A vs. BNo serious adverse events in either groupVomiting: 5% (5/101) vs. 7% (7/96); RR0.68 (95% CI 0.22 to 2.07)Dizziness: 5% (5/101) vs. 4% (4/96); RR1.19 (95% CI 0.33 to 4.29) | Ipca Laboratories | Fair |
| Ralph, 2008 | A vs. BPain, patient-rated impression of pain relief, mean change from baseline day3 (scale 0-4; higher score = greater pain relief): 1.8 vs. 1.1, p<0.0001; day 7 between-group difference p<0.0001 (data not shown)Global improvement, patient-rated impression of change, mean change from baseline at day 3 (scale 0-4; higher score = greater improvement); 2.3 vs.1.7, p<0.0001; day 7 between-group difference p<0.0001 (data not shown) | A vs. BNo serious adverse events in either groupWithdrawals due to adverse events: 3% (8/277) vs. 2% (5/284); RR 1.64 (95% CI0.54 to 4.95)Drowsiness: 13% (37/277) vs. 5% (13/284); RR 2.92 (95% CI 1.59 to 5.37) Dizziness: 10% (27/277) vs. 3% (9/284); RR 3.08 (95% CI 1.47 to 6.42) Headache: 4% (10/277) vs. 1% (4/284); RR 2.56 (95% CI 0.81 to 8.08) | MedPointePharmaceuticals | Fair |

**Please see Appendix C. Included Studies for full study references.**