Review information

Authors

[Empty name][1]

[1][Empty affiliation]

Citation example: [Empty name]. Opioids for fibromyalgia syndrome. Cochrane Database of Systematic Reviews [Year], Issue [Issue].

Characteristics of studies

Characteristics of included studies

Bennett 2003

Methods	RCT, Total duration 91 days, visits at day 1, 14, 28, 56, 91
Participants	Adult subjects aged 18 to 75 years with at least moderate pain from fibromyalgia, defined as 40mm on a 100-mm pain visual analog scale. All subjects fulfilled the 1990 American College of Rheumatology classification guidelines for the diagnosis of fibromyalgia. Subjects were also required to be in general good health, and women were required to be practicing contraception or incapable of pregnancy.
Interventions	Intervention: combination analgesic tablet (37.5 mg tramadol/325 mg acetaminophen) for the treatment of FM pain Control: placebo
Outcomes	Function, quality of life, pain, fatigue/sleep, adverse events, drop-out
Notes	USA. Funding: This study was supported by a grant (CAPSS-113) from Ortho-McNeil Pharmaceutical, Inc, Raritan, New Jersey. All investigators were financially reimbursed by Ortho-McNeil Pharmaceutical for conducting this study

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Subjects were assigned sequentially in 1:1 fashion at each site using a randomized list of medication codes. Comment: Method not described but probably random, no sig baseline differences between groups
Allocation concealment (selection bias)	Low risk	Tramadol/acetaminophen or matching placebo tablets were prepared by the sponsor and dispensed in bottles containing 100 tablets. Each bottle had a two-part tear-off label; study medication identification was concealed and could only be revealed in case of emergency.
Blinding of participants and personnel (performance bias)	Low risk	Treatment assignments were not revealed to study subjects, investigators, clinical staff, or study monitors until all subjects had completed therapy and the database had been finalized.
Blinding of outcome assessment (detection bias)	Low risk	Treatment assignments were not revealed to study subjects, investigators, clinical staff, or study monitors until all subjects had completed therapy and the database had been finalized.
Incomplete outcome data (attrition bias)	High risk	Intervention group: 49% loss. Control: 62% loss
Selective reporting (reporting bias)	Low risk	All data provided
Other bias	Low risk	no other apparent risk of bias

Russell 2000

Methods	RCT. 6 week treatment period after responding to tramadol in an open label run-in phase
Participants	Patient were between 18-75 years , with otherwise good health, met the ACR criteria patient for FM. At entrence they had at least moderat pain (score of 4 on a VAS)
Interventions	Intervention: Tramadol 50 to 400 mg/day. Control: placebo
Outcomes	Function,Pain, Common adverse events, drop-out
Notes	USA. Funding: Reasearch grant from Ortho-McNeil Pharmaceutic al, Raritan, New Jersey

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer generated random numbers
Allocation concealment (selection bias)	Low risk	identically appearing capsules of tramadol HCl and placebo were prepared by the RW Johnson Pharmaceutical Research Institute.
Blinding of participants and personnel (performance bias)	Low risk	Identical appering tramadol and placebo was prepared by RW Johnson Pharmaceutical Research Institute
Blinding of outcome assessment (detection bias)	Low risk	Identical appering tramadol and placebo was prepared by RW Johnson Pharmaceutical Research Institute
Incomplete outcome data (attrition bias)	Low risk	1 drop-out in the intervention group
Selective reporting (reporting bias)	Low risk	data for all outcomes are reported
Other bias	Unclear risk	Only responders included in the controlled phase

Footnotes

Characteristics of excluded studies

Footnotes

Characteristics of studies awaiting classification

Footnotes

Characteristics of ongoing studies

Footnotes

References to studies

Included studies

Bennett 2003

[Empty]

Russell 2000

[Empty]

Excluded studies

Data and analyses

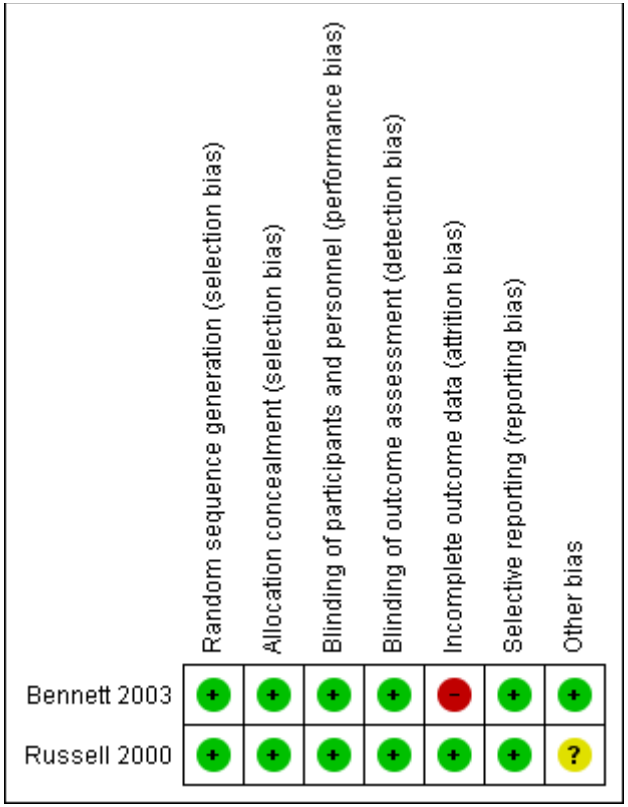
1 Opioids versus placebo at final treatment

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 Pain cm VAS	2		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.1.1 Mean	2	382	Mean Difference (IV, Random, 95% CI)	-1.22 [-1.82, -0.63]
1.2 Sleep index 9	1	313	Mean Difference (IV, Fixed, 95% CI)	0.00 [-3.88, 3.88]
1.3 Drop out	2	384	Risk Ratio (IV, Random, 95% CI)	0.79 [0.65, 0.97]
1.4 Fibromyalgia Impact Questionnaire	2	382	Mean Difference (IV, Random, 95% CI)	-5.43 [-8.68, -2.19]
1.5 SF 36 mental component summary	1	313	Mean Difference (IV, Fixed, 95% CI)	1.00 [-1.66, 3.66]
1.6 Nausea	1	312	Risk Ratio (M-H, Fixed, 95% CI)	1.72 [1.01, 2.95]

1.7 Pruritus	1	312	Risk Ratio (M-H, Fixed, 95% CI)	3.17 [1.30, 7.72]
1.8 Constipation	1	312	Risk Ratio (M-H, Fixed, 95% CI)	3.00 [1.12, 8.05]
1.9 30% pain reduction	1	313	Risk Ratio (M-H, Fixed, 95% CI)	1.77 [1.26, 2.48]
1.10 50% pain reduction	1	313	Risk Ratio (M-H, Fixed, 95% CI)	1.87 [1.26, 2.78]
1.11 Slight pain relief or more	1	69	Risk Ratio (M-H, Fixed, 95% CI)	0.50 [0.31, 0.79]
1.12 Pain relief 'A lot'	1	69	Risk Ratio (M-H, Fixed, 95% CI)	1.94 [0.74, 5.10]
1.13 Function	1	313	Mean Difference (IV, Fixed, 95% CI)	-0.80 [-1.37, -0.23]
1.14 Fatigue	1	313	Mean Difference (IV, Fixed, 95% CI)	-0.30 [-0.83, 0.23]
1.15 Quality of life	1	313	Mean Difference (IV, Fixed, 95% CI)	1.00 [-1.66, 3.66]

Figures

Figure 1



Risk of bias summary: review authors' judgements about each risk of bias item for each included study.