Anticonvulsants for fibromyalgia.

Fibromyalgia (FM) is a clinically well-defined chronic condition of unknown aetiology characterised by chronic widespread pain that often co-exists with sleep problems and fatigue. People often report high disability levels and poor health-related quality of life (HRQoL). Drug therapy focuses on reducing key symptoms and disability, and improving HRQoL. Anticonvulsants (antiepileptic drugs) are drugs frequently used for the treatment of chronic pain syndromes. To assess the benefits and harms of anticonvulsants for treating FM symptoms. We searched the Cochrane Central Register of Controlled Trials (CENTRAL) (Issue 8, 2013), MEDLINE (1966 to August 2013), PsycINFO (1966 to August 2013), SCOPUS (1980 to August 2013) and the reference lists of reviewed articles for published studies and www.clinicaltrials.gov (to August 2013) for unpublished trials. We selected randomised controlled trials of any formulation of anticonvulsants used for the treatment of people with FM of any age. Two review authors independently extracted the data of all included studies and assessed the risks of bias of the studies. We resolved discrepancies by discussion. We included eight studies: five with pregabalin and one study each with gabapentin, lacosamide and levetiracetam. A total of 2480 people were included into anticonvulsants groups and 1099 people in placebo groups. The median therapy phase of the studies was 13 weeks. The amount and quality of evidence were
insufficient to draw definite conclusions on the efficacy and safety of gabapentin, lacosamide and levetiracetam in FM. The amount and quality of evidence was sufficient to draw definite conclusions on the efficacy and safety of pregabalin in FM. Therefore, we focused on our interpretation of the evidence for pregabalin due to our greater certainty about its effects and its greater relevance to clinical practice. All pregabalin studies had a low risk of bias. Reporting a 50% or greater reduction in pain was more frequent with pregabalin use than with a placebo (risk ratio (RR) 1.59; 95% confidence interval (CI) 1.33 to 1.90; number needed to treat for an additional beneficial outcome (NNTB) 12; 95% CI 9 to 21). The number of people who reported being ‘much’ or ‘very much’ improved was higher with pregabalin than with placebo (RR 1.38; 95% CI 1.23 to 1.55; NNTB 9; 95% CI 7 to 15).

Pregabalin did not substantially reduce fatigue (SMD -0.17; 95% CI -0.25 to -0.09; 2.7% absolute improvement on a 1 to 50 scale) compared with placebo. Pregabalin had a small benefit over placebo in reducing sleep problems by 6.2% fewer points on a scale of 0 to 100 (standardised mean difference (SMD) -0.35; 95% CI -0.43 to -0.27). The dropout rate due to adverse events was higher with pregabalin use than with placebo use (RR 1.68; 95% CI 1.36 to 2.07; number needed to treat for an additional harmful outcome (NNTH) 13; 95% CI 9 to 23). There was no significant difference in serious adverse events between pregabalin and placebo use (RR 1.03; 95% CI 0.71 to 1.49).

Dizziness was reported as an adverse event more frequently with pregabalin use than with placebo use (RR 3.77; 95% CI 3.06 to 4.63; NNTH 4; 95% CI 3 to 5). The anticonvulsant, pregabalin, demonstrated a small benefit over placebo in reducing pain and sleep problems. Pregabalin use was shown not to substantially reduce fatigue compared with placebo. Study dropout rates due to adverse events were higher with pregabalin use compared with placebo. Dizziness was a particularly frequent adverse event seen with pregabalin use. At the time of writing this review, pregabalin is the only anticonvulsant drug approved for treating FM in the US and in 25 other non-European countries. However, pregabalin has not been approved for treating FM in Europe. The amount and quality of evidence were insufficient to draw definite conclusions on the efficacy and safety of gabapentin, lacosamide and levetiracetam in FM.

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