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Losigamone add-on therapy for focal epilepsy.
Cochrane Database of Systematic Reviews 2018, Issue 1. Art. No.: CD009324.
DOI: 10.1002/14651858.CD009324.pub4.

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[Intervention Review]

Losigamone add-on therapy for focal epilepsy

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Editorial group: Cochrane Epilepsy Group.
Publication status and date: New search for studies and content updated (no change to conclusions), published in Issue 1, 2018.

Citation: Xiao Y, Luo M, Wang J, Luo H. Losigamone add-on therapy for focal epilepsy. *Cochrane Database of Systematic Reviews* 2018, Issue 1. Art. No.: CD009324. DOI: 10.1002/14651858.CD009324.pub4.

ABSTRACT

Background

Epilepsy is a common neurologic disorder, affecting approximately 50 million people worldwide; nearly a third of these people have epilepsy that is not well controlled by a single antiepileptic drug (AED) and they usually require treatment with a combination of two or more AEDs. In recent years, many newer AEDs have been investigated as add-on therapy for focal epilepsy; losigamone is one of these drugs and is the focus of this systematic review. This is an update of a Cochrane review first published in 2012 (*Cochrane Database of Systematic Reviews* 2012, Issue 6) and updated in 2015.

Objectives

To investigate the efficacy and safety of losigamone when used as an add-on therapy for focal epilepsy.

Search methods

For the latest update on 9 February 2017, we searched the Cochrane Epilepsy Specialized Register, CENTRAL and MEDLINE . We searched trials registers and contacted the manufacturer of losigamone and authors of included studies for additional information. We did not impose any language restrictions.

Selection criteria

Randomized controlled, add-on trials comparing losigamone with placebo for focal epilepsy.

Data collection and analysis

Two review authors independently assessed trial quality and extracted data. The primary outcomes were 50% or greater reduction in seizure frequency and seizure freedom; the secondary outcomes were treatment withdrawal and adverse events. Results are presented as risk ratios (RRs) with 95% confidence intervals (CIs) or 99% CIs (for the individual listed adverse events to make an allowance for multiple testing).

Main results

Two trials involving a total of 467 participants, aged over 18 years, were eligible for inclusion. Both trials assessed losigamone 1200 mg/day or 1500 mg/day as an add-on therapy for focal epilepsy. We assessed one trial as being of good methodological quality while the other was of uncertain quality. For the efficacy outcomes, results did show that participants taking losigamone were significantly more likely to achieve a 50% or greater reduction in seizure frequency (RR 1.76, 95% CI 1.14 to 2.72), but associated with a significant increase of treatment withdrawal when compared with those taking placebo (RR 2.16, 95% CI 1.28 to 3.67). For the safety outcomes, results indicated that the proportion of participants who experienced adverse events in the losigamone group was higher than in the placebo group (RR 1.34, 95% CI 1.00 to 1.80), dizziness was the only adverse event significantly reported in relation to losigamone (RR 3.82, 99% CI 1.69 to

8.64). The proportion of participants achieving seizure freedom was not reported in either trial report. A subgroup analysis according to different doses of losigamone showed that a higher dose of losigamone (1500 mg/day) was associated with a greater reduction in seizure frequency than lower doses, but was also associated with more dropouts due to adverse events.

Authors' conclusions

The results of this review showed that losigamone did reduce seizure frequency but was associated with more treatment withdrawals when used as an add-on therapy for people with focal epilepsy. However, the included trials were of short-term duration and uncertain quality. Future well-designed randomized, double-blind, placebo-controlled trials with a longer-term duration are needed. No new studies have been found since the last version of this review. We judged the overall quality of the evidence for the outcomes assessed as moderate.

PLAIN LANGUAGE SUMMARY

Losigamone add-on therapy for focal epilepsy

Review question

This review is an update of a previously published review in the *Cochrane Database of Systematic Reviews* (2015, Issue 12) on 'Losigamone add-on therapy for focal epilepsy'. We reviewed the evidence about the efficacy and safety of losigamone when used as an add-on therapy for focal epilepsy. We found two studies.

Background

Epilepsy is a common neurologic disorder, affecting approximately 50 million people worldwide; nearly a third of these people have epilepsy that is not well controlled by a single antiepileptic drug (AED) and often require treatment with two or more AEDs (add-on therapy). In recent years, many newer AEDs have been investigated as add-on therapy for focal epilepsy; losigamone is one of these drugs. We wanted to know whether losigamone was an effective and safe treatment for people with focal epilepsy.

Study characteristics

The evidence is current to February 2017. We found two trials assessing add-on losigamone for focal epilepsy, which recruited a total of 467 participants aged over 18 years. Both trials assessed losigamone 1200 mg/day or 1500 mg/day as an add-on therapy for focal epilepsy.

Key results

The results of this review showed that participants taking losigamone as an add-on treatment were more likely to reduce their seizure frequency by 50% or more in the short term; however losigamone was associated with more treatment withdrawal side effects than placebo. The most frequent adverse event caused by losigamone was dizziness.

Quality of the evidence

We assessed one trial as being of good methodological quality while the other was of uncertain quality. We judged the overall quality of the evidence for the outcomes assessed as moderate.