

POEMs



Placebo almost as effective as nonbenzodiazepine hypnotics in adults

Bottom Line:

The nonbenzodiazepine sleep medicines – eszopiclone (not available in UK), zaleplon (Sonata), and zolpidem – allow people to fall asleep faster, though not strikingly faster, than placebo.

When monitored, patients taking placebo fell asleep an average 20 minutes faster than before treatment, and patients taking active treatment fell asleep an average 42 minutes faster (22 minutes faster than placebo). However, when the patients were asked, the difference in perceived sleep onset was only seven minutes faster with active treatment.

The effect of treatment on sleep quality or duration was not measured consistently in these studies, perhaps because of the short duration of these drugs. Higher doses worked better. (LOE = 1a)

Reference:

Huedo-Medina TB, *et al.* Effectiveness of non-benzodiazepine hypnotics in treatment of adult insomnia: meta-analysis of data submitted to the Food

and Drug Administration. *BMJ* 2012; 345:e8343.

Study Design: Meta-analysis (randomised controlled trials) **Funding:** Foundation **Setting:** Various (meta-analysis) **Allocation:** Unknown

Synopsis:

The placebo effect of hypnotics is so profound that the medicines do not even need to be taken for them to work: simply having them available allows some people to sleep better.

The researchers conducting this analysis attempted to tease out the additional benefit of nonbenzodiazepine hypnotics over a placebo effect. They used data submitted by manufacturers to the Food and Drug Administration (FDA), consisting of 13 studies of 4378 patients, which allowed them to combine all the data at the patient level. The average duration of the studies was 33 days. Studies were of high quality and had complete reporting of the data. The authors did not include any research conducted following FDA approval.

Compared with placebo, the hypnotic drugs (eszopiclone, zaleplon and, mostly, zolpidem) produced a slight benefit in sleep latency (how long to fall asleep) as compared with placebo: objectively (as measured by polysomnography), the average difference was 22 minutes; by patient report the difference was only seven minutes. This difference translates into an effect size not considered clinically relevant.

Other outcomes – sleep duration and efficiency – were not measured in enough studies to allow for valid comparison.

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