

<b>Critique author</b>	Ed Whitney
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<b>Bibliographic Data</b>	
Authors	Wen W, Sitar S, et al
Title	A multicenter, randomized, double-blind, placebo-controlled trial to assess the efficacy and safety of single-entity, once-daily hydrocodone tablets in patients with uncontrolled moderate to severe chronic low back pain.
PMID	26111544
Citation	Expert Opin Pharmacother. 2015;16(11):1593-606
Other information if relevant	

<b>Methods</b>	
Aim of study	To assess the efficacy and safety of once-daily hydrocodone for patients with moderate to severe chronic low back pain
Design	Randomized double blind trial preceded by an open-label run-in dose titration period

<b>Reasons not to cite as evidence</b>
<ul style="list-style-type: none"> <li>- The primary efficacy outcome, pain score difference at the end of the 12 week double-blind period, is described only in terms of p values with graphic presentation of data rather than numeric effect sizes</li> <li>- The low p value is likely to be attributable to the fairly large sample size (N=588) with a small therapeutic effect from the appearance of Figure 3 where the primary outcome is displayed</li> <li>- The effect of hydrocodone appears to be in line with that of other opioids for chronic low back pain</li> </ul>

<b>Additional references or comments if relevant</b>
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- There were 905 patients who entered the open-label titration period, and 588 (65%) were randomized to the double blind phase of the trial
- This is also in line with the rates of success seen in previous trials with some form of enriched enrollment based on selecting drug responders in an open-label dose titration period