FULL-LENGTH ARTICLE NPub.org/p6t88c

Lasmiditan is an effective acute treatment for migraine

A phase 3 randomized study

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Study objective
To assess the efficacy of lasmiditan in acute migraine.

Summary results
Lasmiditan is an efficacious treatment for acute migraine.

Classification of evidence
Class I.

What is known and what this paper adds
Triptans are common treatments for migraine but are contraindicated in patients with certain cardiovascular conditions. This study shows that lasmiditan is an efficacious antimigraine therapy that is safe for patients with multiple cardiovascular risk factors.

Participants and setting
This study randomized 2,231 patients who experienced 3–8 migraine attacks per month, had experienced disabling migraine for ≥12 months, and had Migraine Disability Assessment total scores ≥11. This study was conducted between April 27, 2015, and August 12, 2016, through 99 US centers.

Design, size, and duration
This double-blind, phase 3 trial used a central randomization process to assign patients to groups receiving lasmiditan at 200 mg, lasmiditan at 100 mg, or placebo. Participants were instructed to take the issued medication within 4 hours of the onset of the next moderate-to-severe migraine and to subsequently record pain intensities with an electronic diary.

Primary outcome measures
The primary outcome was freedom from headache pain 2 hours after dosing.

Main results and the role of chance
The issued tablets were used by 1,856 participants (83.2%). Compared to placebo, lasmiditan was associated with greater likelihoods of freedom from headache pain 2 hours after dosing at both the 200-mg and 100-mg doses ($p < 0.001$ for both).

Table Efficacy of lasmiditan at providing pain relief

Treatment group	Odds ratio (95% confidence interval) relative to placebo group for freedom from headache pain at 2 h
Lasmiditan 200 mg	2.6 (2.0–3.6)
Lasmiditan 100 mg	2.2 (1.6–3.0)

Harms
The reported adverse events were mostly mild or moderate in severity.

Bias, confounding, and other reasons for caution
The pain-freedom response rate for the placebo group was unusually high.

Generalizability to other populations
The fact that 77.9% of the analyzed participants had cardiovascular risk factors other than migraine favors the generalizability of the results.

Study funding/potential competing interests
This study was funded by CoLucid Pharmaceuticals, an Eli Lilly subsidiary. Some authors report being employed by CoLucid or Eli Lilly; owning stock in healthcare companies, including CoLucid and Eli Lilly; receiving consultancy work, advisory board appointments, and honoraria from scholarly societies, and healthcare companies, including Eli Lilly; being formerly employed by IQVIA, which received contracts from CoLucid; receiving research support from the NIH and foundations; serving on editorial boards; and receiving publication royalties. Go to Neurology.org/N for full disclosures.

Trial registration number
NCT02439320 on ClinicalTrials.gov.

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