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ORIGINAL ARTICLE

Ubrogepant for the Treatment of Migraine

David W. Dodick, M.D., Richard B. Lipton, M.D., Jessica Ailani, M.D., Kaifeng Lu, Ph.D., Michelle Finnegan, M.P.H., Joel M. Trugman, M.D., and Armin Szegedi, M.D.

RobotReviewer report

Abstract

Here are the results from 1 PDFs.

Risk of bias table

trial	design	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment
Dodick DW, 2019	RCT	+	+	+	+

Trial summaries

n	Participants	Interventions	Outcomes	punchline	finding
?? ?	Thirty patients suffering from intractable, repetitive migraine took part	propranolol, Migraine, placebo	frequency of migraine attacks	No notable differences were observed among groups with regard to baseline demographics or clinical characteristics (Table 1 and Table S2).	‚Äï no diff

Characteristics of studies

Dodick DW, 2019

Population	1. Trial Participants Participants were eligible if they were 18 to 75 years of age, had at least a 1-year history of mi- graine, with or without aura, that met the criteria specified in the International Classification of Head- ache Disorders, 3rd edition (beta version), 12 and had had migraine onset before the age of 50 years. 2. na l o f m e dicine who had taken an acute migraine treatment on 10 or more days in any of the 3 months before screening or who had participated in a trial with an injectable monoclonal antibody against CGRP or the CGRP receptor were excluded. 3. If participants did not take a dose of ubrogepant or placebo to treat a qualifying migraine attack (i.e., a migraine headache with moderate or severe pain) within 60 days after randomization, they were with- drawn from the trial.

Intervention	1. The placebo group received two tab- lets of placebo, the 50-mg ubrogepant group received one 50-mg tablet of ubrogepant and one tablet of placebo, and the 100-mg ubrogepant group received two 50-mg tablets of ubrogepant. 2. Participants were ran- domly assigned in a 1:1:1 ratio, with the use of an automated Web-response system, to receive placebo, ubrogepant at a dose of 50 mg, or ubro- gepant at a dose of 100 mg. 3. The optional second dose was taken by 222 participants in the placebo group, 184 in the 50-mg ubrogepant group (of whom 107 were randomly assigned to receive 50 mg of ubroge- pant and 77 to receive placebo for the second dose), and 198 in the 100-mg ubrogepant group (of whom 93 were randomly assigned to receive 100 mg of ubrogepant and 105 to receive placebo for the second dose).
Outcomes	1. Secondary efficacy end points were pain relief (defined as a change in the severity of headache pain from moderate or severe pain to mild pain or no pain) at 2 hours after the initial dose, sus- tained pain relief (defined as pain relief during the period from 2 to 24 hours after the initial dose without the use of the optional second dose or rescue medication), sustained freedom from pain (defined as freedom from pain during the period from 2 to 24 hours after the initial dose without the use of the optional second dose or rescue medication), and absence of photophobia, absence of phonophobia, and absence of nausea, all at 2 hours after the initial dose (Table S1 in 2233 Ubrogepant for the Treatment of Migr aine Supplementary Appendix, available at NEJM.org). 2. Overall satisfaction with migraine treatment, also a prespecified, explor- atory efficacy end point, was evaluated with the use of a 7-point rating scale (with higher values indicating greater satisfaction) at 2 hours and 24 hours after the initial dose. 3. The total number is the number of participants for whom status with respect to sustained pain relief or sustained freedom from pain could be determined on the basis of the reported headache severity at scheduled time points, the use of rescue medication or optional second dose between 2 and 24 hours after the initial dose, and participants' report of whether they had recurrence of headache pain at 24 hours.

Bias	Judgement	Support for judgement
Random sequence generation	low	1. Participants were ran- domly assigned in a 1:1:1 ratio, with the use of an automated Web-response system, to receive placebo, ubrogepant at a dose of 50 mg, or ubro- gepant at a dose of 100 mg. 2. Participants in the ubrogepant groups underwent rerandomiza- tion for the optional second dose; those who had been assigned to the 50-mg ubrogepant group for the initial dose received either two tablets of placebo or one 50-mg tablet of ubrogepant and one tablet of placebo, and those who had been assigned to the 100-mg ubrogepant group for the initial dose received either two tablets of placebo or two 50-mg tablets of ubrogepant. 3. If participants did not take a dose of ubrogepant or placebo to treat a qualifying migraine attack (i.e., a migraine headache with moderate or severe pain) within 60 days after randomization, they were with- drawn from the trial.
Allocation concealment	low	1. Participants were ran- domly assigned in a 1:1:1 ratio, with the use of an automated Web-response system, to receive placebo, ubrogepant at a dose of 50 mg, or ubro- gepant at a dose of 100 mg. 2. The participants, site personnel, and trial- sponsor personnel were unaware of the group assignments. 3. These cases were adjudicated by an independent review committee whose members were unaware of the trial-group assignments; four of the six cases were considered most likely not related to the trial regimen on the basis of identification of alternative causes or

		confound- ing factors.
Blinding of participants and personnel	low	1. The participants, site personnel, and trial- sponsor personnel were unaware of the group assignments. 2. Trial Procedures The trial tablets were identical in appearance and were provided to participants in identical blister cards to maintain masking of trial-group assign- ments. 3. Participants in the ubrogepant groups underwent rerandomiza- tion for the optional second dose; those who had been assigned to the 50-mg ubrogepant group for the initial dose received either two tablets of placebo or one 50-mg tablet of ubrogepant and one tablet of placebo, and those who had been assigned to the 100-mg ubrogepant group for the initial dose received either two tablets of placebo or two 50-mg tablets of ubrogepant.
Blinding of outcome assessment	low	1. The participants, site personnel, and trial- sponsor personnel were unaware of the group assignments. 2. Safety Data on adverse events were collected and evalu- ated by the investigators, who were unaware of the trial-group assignments, 48 hours after the initial dose, 48 hours after the optional second dose, and within 30 days after the last dose. 3. Trial Procedures The trial tablets were identical in appearance and were provided to participants in identical blister cards to maintain masking of trial-group assign- ments.

References

1. Dodick DW et al. Ubrogepant for the Treatment of Migraine Postgrad Med J 2019. 23; 2230-2241 PMID: 787958