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Placebo response in clinical randomized trials of analgesics in migraine.

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The objective was to assess the placebo response in randomized clinical trials of analgesics in the treatment of migraine attacks.

We included placebo-controlled studies that used the criteria of the International Headache Society for the diagnosis of migraine and headache response as the primary efficacy parameter. In the 11 studies that qualified for inclusion, headache response occurred after placebo treatment in 7-50% of the migraineurs with an average placebo response rate of 30% (95% confidence interval (CI) 23-36). Two hours after treatment with placebo an average of 9% (95% CI 7-12, range 7-17%) of the patients were found to be pain free.

In conclusion, the average headache response rate to placebo was 30% in randomized clinical trials of analgesics in migraine with a tremendous variation among studies.

Placebo response rates vary with the choice of primary efficacy measure as well as patient characteristics and study design.

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