

Understanding endpoints in migraine prevention clinical trials

Media factsheet

Clinical trials

In clinical trials of migraine prevention treatments, different endpoints are used to see how effective a treatment has been.

About endpoints

What is an endpoint and why are they significant in migraine trials?

- An endpoint in a clinical trial is an outcome that can be measured to show whether the intervention or treatment being studied is beneficial
- One endpoint commonly used in migraine prevention clinical trials is the reduction in mean monthly migraine days
- This simply tells you the difference between how many average days of migraine per month the entire groups had before and after the trial
- Statistical analyses can be used to compare the difference in the placebo group with the difference found in the treatment group. However, this endpoint does not indicate how individual patients respond to treatment
- Therefore, another endpoint is commonly assessed in trials, called the 50% responder rate. This endpoint is more patient centric and takes the individual migraine burden at baseline into account
- This endpoint looks at how many people have their number of migraine days cut by half or more by the end of the study; a reduction of at least half is widely accepted as clinically meaningful for patients by healthcare practitioners, patients and regulatory bodies¹
- So, for example, a patient with 8 migraine days at baseline would need to go down to 4 migraine days or fewer to be called a “50% responder”
- You may also see it written as the number of patients experiencing a reduction in migraine days of $\geq 50\%$
- The proportion of people receiving treatment who have this reduction can be compared to the proportion of those receiving placebo using statistical analyses. The difference can be seen as an indicator of the effect of treatment
- You may also see a 100% reduction in monthly migraine days reported – this indicates the proportion of patients who are migraine free (do not report any migraine days in a given month)

References

1. Tfelt-Hansen P, Pascual J, Ramadan N, et al. Guidelines for controlled trials of drugs in migraine: third edition. A guide for investigators. Cephalalgia. 2012; 32(1):6-38.

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