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Placebo response in migraine

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Glostrup 14 Sep. 2010-09-14

To the Editor of Eur J Clin Pharmacol

Sir

I'm currently in the process of revising the Guidelines for Drug Trials in Migraine of The International Headache Society, When browsing the literature for information about the placebo response in migraine randomised clinical trials (RCTs) I read with interest the extensive meta-analysis on this subject published by Macedo et al in Eur J Clin Pharmacol [1]. There is, however, one fundamental misunderstanding, namely the definition of headache relief. It is stated that headache relief is a 50% reduction in pain [1]:The standard was that all migraine should have moderate or severe headache before drug administration and headache relief as defined by Glaxo [2] was a decrease in headache from moderate (2) or severe (3) to none (0) or mild (1) at one hour (subcutaneous sumatriptan) or two hours (oral and intranasal triptans), So a success, headache relief, could be either 3-0, 3-1, 2-0, or 2-1.

The placebo response depends on many factor such as design, route of administration, and cultural factor, eg. Europe vs. North America [1]. In addition, it could be important whether the patients are treated as in-patients in headache clinic or treat themselves at home. In one crossover RCT with a subcutaneous autoinjector with sumatriptan 6 mg migraine patients were recruited from general practice and treated migraine attacks at home. Headache relief was 61% after active drug and 6% after placebo at 60 min [3]. The therapeutic gain (TG) was 55% (95% CI: 44% to 65%), Thus the placebo result was extremely low but the TG was similar to the TG of 49% [1] and 51% [4] in meta-analyses.

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4 Finally, there is an increasing tendency to use pain free at 2 h as the primary efficacy measure in
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7 RCTs on acute treatment migraine.[5] and pain free is what the migraine patients want [6]
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14 Yours sincerely
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