THE USE OF PLACEBO IS ESSENTIAL IN HEADACHE TRIALS-NO

Prof. Dimos D. Mitsikostas, MD, PhD.

Medicine is based on placebo than millennia since man first became conscious of himself and this continues today. Because pain is not only a sensory but an emotional experience as well, brain modifies pain perception considerably. Thus, placebo effects for pain and headache appear maximal while placebo effects for outcomes like cancer survival appear to be minimal. In randomized controlled studies (RCTs) for headache prevention and acute treatment placebo effect reaches 30% approximately. Interestingly, the benefits of placebo persist even if placebo is honestly described indicating that whether treatment involves medication or placebo, the information provided to patients and the ritual of pill taking are important components of care (Kam-Hansen et al., 2014). Thus, placebo and medication effects can be modulated by expectancies. There is good evidence that several agents are superior to placebo for almost all primary headache disorders so far. Patients treated with placebo do experience adverse effects in addition (nocebo effect, Mitsikostas et al., 2015) demonstrating crucial ethical concerns. These observations indicate that the use of placebo in headache RCTs is not as much essential as we used to believe before, because the headache treatment itself includes the placebo already, as in clinical practice. In the contrary, head-to-head comparisons of drugs in RCTs remain indispensable and practical.