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Impact of the nocebo effect in clinical studies of painful diabetic peripheral neuropathy: Can this effect masquerade a safety signal of a new investigational compound?

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Randomized, double blind, placebo controlled studies are `the gold standard` of Painful Diabetic Peripheral Neuropathy (DPNP). The nocebo effect represents the manifestation of side effects in clinical setting during placebo treatment. This can be considerable with side effects of any kind and severity within those in the label of an active study comparator, which is also recommended in confirmatory study designs. Accordingly to a recent analysis in 62 studies involving 5,095 patients with DPNP this effect contributed to 5.8% of subject`s discontinuations. Any attempt to mitigate the nocebo effect may improve the overall tolerability profile of placebo and ultimately the retention rate of subjects in a clinical setting. In addition and no less importantly, the nocebo effect can potentially masquerade an early safety signal from a newly tested compound. Side effects of currently available pain medications as well as newly tested molecules can be with high rate of incidence and severe by intensity. Typically the most relevant side effects are CNS-related including somnolence, dizziness, and abuse potential, gastrointestinal, cardiovascular, edema, weight gain, ophthalmological disturbances, impotence and increased risk of suicide. The danger from these side effects is considerable. It is vital to define a clinical safety plan with an Independent Safety Monitoring Committee to assess side effects of relevance in un-blinded fashion during the course of clinical studies and to ultimately establish causality relationship based on patient history and concomitant medications. This may allow the early detection of a safety signal, which otherwise might be obscured by the nocebo effect.

Biography

Domenico Merante completed his Medical degree in 1988 at the age of 25 and in 1993 became specialist of endocrinology and diabetes, both degrees obtained at Pisa University/Italy and St. Chiara Hospital, Pisa. He is currently Senior Director of Clinical Development of Daiichi Sankyo Development Ltd. in the UK. He previously worked at GSK, Eli Lilly, Novo Nordisk and Lab. Guidotti. He has dedicated over 20 years in the pharmaceutical industry mainly working in diabetes, endocrinology, hypertension and neuropathic pain areas of research. He has published 21 papers and 18 abstracts in reputed journals as main or co-author.

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