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Challenges in painful diabetic peripheral neuropathy clinical research

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Randomised, double blind, placebo controlled studies are required in neuropathic pain clinical research arena. Few drugs are approved for neuropathic pain indications as typically they lose therapeutic response over time and have a far from ideal tolerability risk profile. Major challenges in this area of clinical research reflect the nature of neuropathic pain itself, which is a heterogeneous and subjective disorder. These are linked to: a) Subjective variability in symptoms; b) Low response rates to current therapies; c) Poly-pharmacy treatments; d) Side effects of current therapies impairing responsiveness to active medications.

In addition, some other challenges in neuropathic pain research area were identified:

1) Difficulty to translate preclinical data into clinical

2) Washout and rescue medications and patients selection bias

3) High placebo response

4) Nocebo effect

5) Challenging and different requirements from regulatory agencies

Amongst these challenges, the placebo response represents the most significant one in clinical trials of Painful Diabetic Peripheral Neuropathy (PDPN) as well as in many other neuropathic pain conditions. Several studies failed because the primary endpoint of statistical superiority to placebo and a clinically relevant reduction of ADPS (Average Daily Pain Score) were not achieved. The dangers of treating acute and chronic pain with opioids, Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) or acetaminophen are considerable. Any effort to mitigate the placebo response in painful DPN clinical trials may support the development of better analgesic treatments. In addition, a better understanding of subjects' typology would be of great help to identify those who really need a pharmacological approach.

Biography

Domenico Merante completed his MD in 1988 at the age of 25 from Pisa University/Italy, School of Medicine. He specialized in endocrinology and diabetes from Pisa University in 1993. He is Director of Clinical Development at Daiichi Sankyo Development Ltd in the UK since 2007. Previously he worked at GSK in Verona, Eli Lilly in Florence, Novo Nordisk in Crawley/UK and Laboratori Guidotti in Pisa. Over 20 years spent in the pharma industry his areas of research are diabetes, endocrinology, hypertension and neuropathic pain. Dr Merante has published 21 papers and 16 abstracts in reputed journals as main or co-author.

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