
METHODS: Search strategies were developed to identify English-language clinical trials, randomized controlled trials (RCTs), and systematic reviews published from 1995 to 2015. The search included trials located in the Pubmed, NHSE, and NICE databases. A total of 956 trials were identified, and 23 were selected for further analysis.

RESULTS: Most of the trials were non-randomized (15), had small sample sizes (11), and were not blinded (10). The number of patients in the trials varied widely, from 9 to 530. The duration of treatment also varied, from 1 to 24 months. The methodological quality of the trials was generally low, with a median Jadad score of 1 (0-4).

CONCLUSIONS: The methodological quality of the trials was generally low, with a median Jadad score of 1 (0-4). The small sample sizes and short duration of treatment may have limited the ability of the trials to detect meaningful differences in outcomes. Further research is needed to improve the methodological quality of clinical trials in the field of epilepsy.

PMR229 DO WE NEED TO STRENGTHEN STUDY DESIGN IN OBSERVATIONAL STUDIES? Longensi C, Simonetti P, Martinucci F. Medineos Observational Research, Modena, Italy

OBJECTIVES: Guidance and standards are made available by the European Network of Centres for the Evaluation of Medicines (ENCePP) and the European Medicines Agency (EMA) to raise the methodological quality of clinical trials and observational studies. Standards for observational study design were issued by the EMA in 2010, the ENCePP Checklist for Study Protocols in 2011, and the ENCePP Guide on Methodological Standards in Pharmacoepidemiology in 2014. We aim to describe the use of the ENCePP standards and to assess the extent to which they are followed in real-world research.

METHODS: We searched clinical trial registries (www.clinicaltrials.gov) and publicly available minutes of meetings of the Standing Committee on Medical Assessment and Evaluation (PRAC) of the European Medicines Agency (EMA). We also searched for guidance and standards from the EMA and the ENCePP and for publications on the use of these standards. We included all trial reports published from 2010 to 2014.

RESULTS: We identified 158 trial reports for 154 trials. The use of ENCePP standards varied widely. The most common standards used were those on study design (77%), data analysis (72%), and safety monitoring (67%). The most common reasons for failure to meet ENCePP standards were lack of methodological expertise (44%) and insufficient resources (36%). The most common standard not met was that on study design (61%).

CONCLUSIONS: There is a need to strengthen study design in observational studies. The ENCePP standards can be used to improve the methodological quality of observational studies. However, further research is needed to identify the barriers to the implementation of these standards and to develop strategies to overcome them.