Understanding of Influence on Placebo Response by Investigators and Site Staff in CNS Clinical Trials

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ABSTRACT

There is increased concern with signal detection capability in part due to increased placebo response in the US (1-3). The attitudes of investigators and their staffs with respect to their ability to influence placebo response is largely unexplored.

METHODS: 65 US site investigators and staff attending an industry-sponsored investigator meeting for a double-blind placebo controlled bipolar depression clinical trial answered questions administered by an audience response system addressing their ability to influence placebo response. The association of responses to role in the study, number of previous trainings aimed at reducing placebo response, proportion of time spent in clinical activities or care unrelated to research, and the source of patients were evaluated using exact chi-square test statistics.

RESULTS: 67.7% (n=52) had previously been in training to reduce placebo response. 41.7% (n=25) identified themselves as “Investigators/Sub-Investigators” and 58.3% (n=35) as “Study Coordinators/Raters” to agree that “Placebo response is largely determined by factors outside of my control” (p=0.03). Otherwise, attitudes toward placebo response did not vary significantly with respect to role (Investigator/Sub-investigator vs. Study Coordinators/Raters) or previous trainings aimed at reducing placebo response. 41.7% (n=25) identified themselves as “Study Coordinators/Raters” and 58.3% (n=35) as “Investigators/Sub-Investigators”.

CONCLUSIONS: Investigators and their staffs with respect to their ability to influence placebo response is largely unexplored. Further research should investigate which approaches to placebo response minimization are most effective.

REFERENCES


BACKGROUND

There is increased concern with signal detection capability in part due to increased placebo response in the US (1-3). Expectation of improvement is a major factor in placebo response (4) that may be modifiable at the site level. The attitudes of investigators and their staffs with respect to their ability to influence placebo response is largely unexplored.

METHODS

65 US site investigators and staff attending an industry-sponsored investigator meeting for a double-blind placebo controlled bipolar depression clinical trial, answered questions administered by an audience response system addressing their ability to influence placebo response. 87.7% (n=52) had previously been in training to reduce placebo response. 41.7% (n=25) identified themselves as “Study Coordinators/Raters” and 58.3% (n=35) as “Investigators/Sub-Investigators”.

The associations of responses to role in the study, number of previous trainings aimed at reducing placebo response, proportion of time spent in clinical activities or care unrelated to research, and the source of patients were evaluated using exact chi-square test statistic.

RESULTS

41.7% (n=25) identified themselves as “Study Coordinators/Raters” and 58.3% (n=35) as “Investigators/Sub-Investigators”. Investigators/Sub-investigators were more likely to endorse “Placebo response is largely determined by factors outside of my control” (p=0.03). Otherwise, attitudes toward placebo response did not vary significantly with respect to role (Investigator/Sub-investigator vs. Study Coordinators/Raters) or previous trainings aimed at reducing placebo response. 41.7% (n=25) identified themselves as “Study Coordinators/Raters” and 58.3% (n=35) as “Investigators/Sub-Investigators”.

REFERENCES

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