Bayesian Hierarchical Modeling and Dose Finding in Alzheimer's Disease

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Light refreshments provided

Abstract

We consider designing phase II clinical trials for Alzheimer's disease, which is typically the proof-of-concept stage for drug development. In such a dose ranging study, multiple doses of the new agent are investigated to identify the most appropriate dose or multiple doses that may have disease modification or symptomatic effects, which would be moved forward to phase III clinical trials for confirmative testing. For this purpose, we develop Bayesian hierarchical modeling for longitudinal measurements, and incorporate the posterior predictive outcome of disease deterioration into decision making. At the interim analysis, any dose arm that shows futility would be dropped earlier, so that the rest of patients in the trial would be allocated to the remaining active arms. We conduct extensive simulation studies to show the satisfactory performance of the proposed Bayesian hierarchical modeling and dose finding approach. Our method can pinpoint the right doses in terms of both tolerability and therapeutic effects.

Biographical Note

Dr. Guosheng Yin received Ph.D. in Biostatistics from the University of North Carolina at Chapel Hill in 2003. He is currently an Associate Professor at University of Hong Kong, and Adjunct Associate Professor at M.D. Anderson Cancer Center. He is a Fellow of the American Statistical Association and an elected member of the International Statistical Institute. He is Associate Editor for the Journal of American Statistical Association, Bayesian Analysis, and Contemporary Clinical Trials. His main research areas include Bayesian adaptive design in clinical trials and survival analysis. He has published over 80 peer-reviewed papers and a book on "Clinical Trial Design" in the John Wiley Series.

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[1] The PI Biostatistics Seminar Series is held on Tuesdays at New York State Psychiatric Institute. If you are interested in receiving regular announcements for our seminars in the future, or if you need further information, please contact Jina James (jamesji@nyspi.columbia.edu, (212) 543-5589).