O-48 - THE INTERNATIONAL STUDY TO PREDICT OPTIMIZED TREATMENT - IN DEPRESSION: RATIONAL, DESIGN AND INITIAL FINDINGS

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Background: The aim of iSPOT-D is to identify biological pretreatment measures that predict or moderate MDD treatment response or remission to escitalopram, sertraline or venlafaxine; and develop a model that incorporates multiple predictors and moderators.
Methods/design: The iSPOT-D study is a multi-center, international, randomized, prospective, open-label trial (1). It is enrolling 2016 MDD outpatients (ages 18-65) from primary or specialty care practices (672 per treatment arm; 672 age-, sex- and education-matched healthy controls). Study-eligible patients are antidepressant medication (ADM) naïve or washed-out with no protocol ADM contraindications. Baseline assessments include symptoms; distress; daily function; cognitive performance; electroencephalogram and event-related potentials; heart rate and genetic measures. A subset of these baseline assessments are repeated after eight weeks of treatment. Outcomes include the 17-item Hamilton Rating Scale for Depression (primary) and self-reported depressive symptoms, social functioning, quality of life, emotional regulation, and side-effect burden (secondary). Participants may then enter a naturalistic telephone follow-up at weeks 12, 16, 24 and 52. The first half of the sample will be used to identify potential predictors and moderators, and the second half to replicate and confirm.
Discussion: First enrolment was in December 2008, and enrollment of the first 50% (1008 MDD participants) was completed in Dec 2010. iSPOT-D evaluates clinical and biological predictors of treatment response in the largest known sample of MDD collected worldwide.
Conclusion: Initial findings reveal a remission rate of 45.4% and a response rate of 62.6% after 6-8 weeks of treatment. Initial findings will be discussed including factors for response prediction and MDD subtype differences.

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