Feasibility of a fully remote, Phase II, interventional decentralized clinical trial in major depressive disorder: Lessons learned

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Methodological Issue Being Addressed There is growing interest in decentralized clinical trials (DCTs) due to their patient-centric design; procedures can be conducted remotely. This means patients can participate from their homes without visiting specific study sites. DCTs may therefore facilitate the conduct of clinical trials by reducing drop-out rates. However, it is uncertain whether a fully remote, interventional DCT is feasible in major depressive disorder (MDD).

Introduction BI 1358894, a novel transient receptor potential canonical 4/5 channel inhibitor, is in development for MDD. Using a fully remote DCT design, the efficacy and safety of adjunctive BI 1358894 versus placebo were investigated in MDD. The key learnings from conducting a DCT were collated to improve future DCTs.

Methods A fully remote, Phase II, double-blind, parallel-group DCT (NCT04423757/1402-0014) was conducted from a (meta)site in the United States. Patients were 18–65 years old with MDD and inadequate responses to first-line antidepressants at screening, ≥moderate disease severity (Montgomery-Åsberg Depression Rating Scale [MADRS] total score ≥22), and receiving ongoing antidepressant monotherapy for ≥8 weeks. Patients were randomized 1:1 to BI 1358894 125 mg or placebo for 6 weeks; treatments were shipped directly to patients' homes. A smartphone application was used to monitor medication adherence using facial recognition technology as well as issue medication reminders and intervene when medication was interrupted. The primary efficacy endpoint was change from baseline in MADRS total score at Week 6. Secondary endpoints included several patient-reported instruments. Safety was also assessed. At the end of the DCT, patient experience was assessed using a patient-feedback questionnaire. During the DCT, mobile nurses visited patients' homes to complete trial procedures (collecting vitals and laboratory samples, assisting with trial devices, electrocardiograms, telemedicine physical exams, and trial medication administration). Clinician-administered assessments and patient-reported instruments were conducted via telemedicine or smartphones, respectively. A study platform scheduled study visits, collated data, and enabled communication between key stakeholders. Feasibility was assessed based on whether it was possible to execute the trial per protocol.

Results This DCT was successfully executed per protocol. The DCT had a vast geographical reach (80,836 patients signed up for the trial) and a high (98%) completion rate. The shipping of trial medication, equipment, and bio-samples to and from patients' homes was effectively handled, and use of the smartphone application for medication monitoring was convenient. Furthermore, the

study platform enabled real-time data collection, efficient communication between patients and trial staff, and convenient scheduling of study visits. Overall, patients reported a positive experience of the DCT. However, several limitations were observed. Recruitment was slow; various optimization strategies were implemented to improve recruitment, but the stringent eligibility criteria resulted in screening failures and a low (n=45) number of patients being randomized within 22 months. Therefore, the trial was terminated early, and it was not possible to statistically analyze the efficacy endpoints.

Conclusion Overall, this first-of-its-kind, fully remote, interventional DCT in MDD was generally feasible and well perceived by participating patients. However, recruitment was not sufficient to assess efficacy. To improve enrollment for future DCTs, learnings regarding recruitment strategies and trial design should be considered.

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Keywords

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Guidelines I have read and understand the Poster Guidelines

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