How can I find out more information?

Use the QR code to learn more about the study

NCT06280235

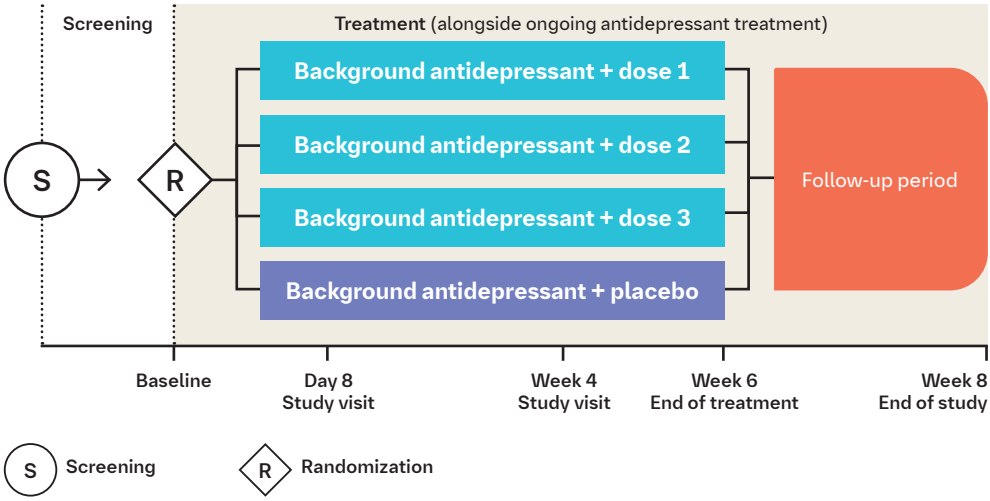
A Phase II Trial Recruiting Patients With Major Depressive Disorder for Adjunctive Treatment

What is the study objective?

To evaluate the efficacy, tolerability, and safety of different doses of BI 1569912, a negative allosteric modulator (NAM) of the NMDA receptor NR2B subunit, as adjunctive therapy in patients with major depressive disorder (MDD)

What is the study design?

A Phase II, 6-week, multicenter, randomized, double-blind, placebo-controlled, dose-finding trial (NCT06280235)



BI 1569912 is an investigational molecule that has not been approved by regulatory authorities for commercial use in patients. Its safety and efficacy have not been established.

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What are the outcome measures?

- Change from baseline in MADRS total score at Day 8
- Change from baseline in MADRS total score at Week 6
- Treatment response defined as ≥50% reduction in MADRS from baseline at Day 8 and Week 6
- Remission defined as MADRS total score ≤10 at Week 6
- Change from baseline in SMDDS total score at Day 8 and Week 4

What are the inclusion criteria?

- Age 18–65 years
- Established diagnosis of MDD, as confirmed by the MINI, with the current depressive episode lasting ≥8 weeks
- HDRS-17 severity score >17
- Insufficient treatment response (<50% response to ≤4 antidepressants) in current episode

What are the exclusion criteria?

- Diagnosis of schizophrenia, schizoaffective disorder, schizophreniform disorder, bipolar disorder, or delusional disorder, as confirmed by the MINI
- Diagnosis of antisocial, paranoid, schizoid, or schizotypal personality disorder or MDD with psychotic features per the DSM-5 criteria
- Diagnosis of any other mental health condition that was the primary focus of treatment ≤6 months prior to screening
- Current or recent history of clinically significant suicidal ideation with intent ≤3 months prior to screening
- Diagnosis of moderate-to-severe substance-related condition ≤6 months prior to screening

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DSM-5, Diagnostic and Statistical Manual of Mental Disorders, 5th edition; GAD-7, Generalized Anxiety Disorder 7-item scale; HDRS-17, Hamilton Depression Rating Scale 17 items; MADRS, Montgomery–Åsberg Depression Rating Scale; MDD, major depressive disorder; MINI, Mini International Neuropsychiatric Interview; NMDA, N-methyl-D-aspartate; NR2B, N-methyl-D-aspartate receptor subtype 2B; SMDDS, Symptoms of Major Depressive Disorder Scale.

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