

Treating insulin Resistance to Improve Outcome in Bipolar Disorder (TRIO-BD)

If you have bipolar disorder and symptoms of depression, would you consider participating in a research study to help researchers discover whether treating insulin resistance (also known as “pre-diabetes”) helps improve mood symptoms?

What is the TRIO-BD study?

The study is a clinical trial in which patients with bipolar disorder, insulin resistance and symptoms of depression will be randomized to metformin (an insulin sensitizing drug) or placebo. In previous studies, we have found that people with bipolar disorder and insulin resistance have a more chronic course of illness, more rapid cycling of mood episodes and poorer response to mood stabilizing treatment. People who are overweight or obese are at higher risk of having insulin resistance, although this can also occur in people of healthy weight. Treating insulin resistance in people with bipolar disorder may be a novel strategy for improving outcome in treatment-resistant bipolar disorder.

What should I expect when participating?

We ask that participants come for an initial interview and have a blood test to determine if they have insulin resistance. The clinician seeing you will also complete two questionnaires to make sure that you meet other criteria for participation. If you are eligible to participate, you have a 50% chance of receiving either metformin or placebo. Neither you, nor any of the researchers, will know whether you are receiving drug or placebo. You will be seen two weeks after starting this treatment and then will be seen every month for a total of 26 weeks. Your other mood stabilizing medications will remain unchanged, except if your dose requires adjustment to keep your blood levels in the therapeutic range. You will be asked to complete a questionnaire at each visit and the clinician seeing you will complete several questionnaires regarding mood symptoms. You will have your weight, blood pressure and waist and hip circumference measured at each visit.

What about personal expenses for participating in the study?

You will receive drug or placebo free of charge. If you need help paying for parking or bus fare, to attend study appointments, please provide us with your receipts so that we can reimburse you.

Funding and ethical approval

This study is funded by the Stanley Medical Research Institute. The TRIO-BD protocol has been reviewed by Health Canada, the Food and Drug Administration and the Nova Scotia Health Authority Research Ethics Board and has received approval.

Would you like to find out more about TRIO-BD?

You can read more about the TRIO-BD study at ClinicalTrials.gov using the identifier: NCT02519543

If you are interested in participating, please contact Peter Menzies at Tel: (902) 473-8040 OR

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