

# Abstract

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## Inositol augmentation of lithium or valproate for bipolar depression.

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**OBJECTIVE:** Despite promising new therapies, bipolar depression remains difficult to treat. Up to half of patients do not respond adequately to currently approved treatments. This study evaluated the efficacy of adjunctive inositol for bipolar depression.

**METHODS:** Seventeen participants with DSM-IV criteria for bipolar depression and a 17-item Hamilton Rating Scale for Depression (HRSD)  $\geq 15$  on proven therapeutic levels of lithium or valproate for  $>2$  weeks were randomized to receive double-blind inositol or placebo for 6 weeks. At the end of double-blind treatment, subjects were eligible for an 8-week open-label trial of inositol.

**RESULTS:** Response was defined a priori as  $>50\%$  reduction in the HRSD and a Clinical Global Impression of 1-2. Four of nine subjects (44%) on inositol and zero of eight subjects on placebo met response criteria ( $p = 0.053$ ). There was no difference between groups in the average change score for the HRSD or Young Mania Rating Scale (YMRS). Response to inositol was highly variable. Of nine subjects randomized to inositol, two had  $>50\%$  worsening in HRSD scores at the end of treatment, three had no change and four had  $>50\%$  improvement. Those who had worsening in depressive symptoms on inositol had significantly higher scores at baseline on the YMRS total score and irritability, disruptive/aggressive behavior and unkempt appearance items.

**CONCLUSIONS:** There was a trend for more subjects on inositol to show improvement in bipolar depression symptoms, but, on average, inositol was not more effective than placebo as an adjunct for bipolar depression. Baseline levels of anger or hostility may be predictive of clinical response to inositol.

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