

Multicenter, double-blind, placebo-controlled trial. Patients with UC who received steroids &/or immunosuppressants for 4 months within the 12 previous months with Mayo score >6 were randomized to receive methotrexate 12.5mg weekly or placebo added to their treatment for 9 months.

Primary endpoints: Proportion of patients entering first remission and the time to reach that remission. In those achieving remission, the maintenance of remission was evaluated.

Results: N=67

- First clinical remission achieved, 46.7% MTX vs 48.6% placebo
- Time to remission 4.1+/-1.9 months MTX vs 3.4+/- 1.7 placebo.
- Proportion of patients that relapsed after achieving remission 64.3% MTX vs 44.4% placebo, p=ns

Conclusion:

Methotrexate at a weekly oral dose of 12.5mg was not found to be better than placebo in the induction or maintenance of remission in active UC.

Methotrexate in Chronic Active Ulcerative Colitis: A Double-Blind, Randomized, Israeli Multicenter Trial

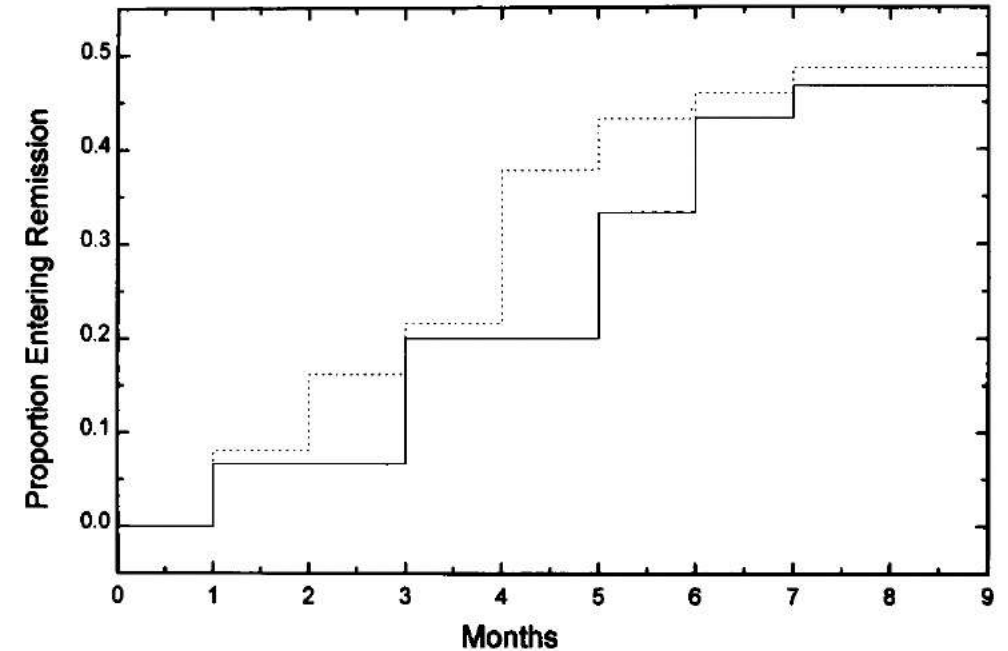


Figure 1. Kaplan–Meier survival analysis was used to compare the cumulative proportion of patients entering first remission in both groups during each study month. —, Methotrexate group; ···, placebo group.

