

48 week trial → 16-week open label MTX induction followed by 32-week double-blind placebo controlled

- MTX 25mg/wk and 12-w steroid taper → At w16 steroid free responders randomly assigned to continue with MTX or placebo.

Primary outcome: Steroid-free remission w48

Results:

- 51% achieved response at week 16 and were included in the maintenance study.

Maintenance study:

- Relapse occurred in 60% of the pbo group and 66% of the MTX group.
- At w48, 30% pbo vs 27% MTX were in steroid-free remission.

Conclusions:

MTX was not superior to placebo in preventing relapses of UC in patients who achieved steroid-free response during induction therapy.

