

Risankizumab as maintenance therapy for moderately to severely active Crohn's disease: results from the multicentre randomised Double-blind placebo-controlled, withdrawal phase 3 FORTIFY Maintenance trial

Phase 3, multicentre, randomised, double-blind, placebo-controlled, maintenance withdrawal study.

Moderately-severe active CD patients who responded in ADVANCE or MOTIVATE induction trials, entered FORTIFY and were randomly assigned to SC RISA 180mg, SC RISA 360mg or withdrawal receiving placebo every 8 weeks.

Corimary endpoint: clinical remission and endoscopic response w52.

Results:

- Clinical remission w52: 52% RISA360, 55% RISA 180 vs 41% placebo.
- Stool frequency and abdominal pain remission, 52% RISA360 vs 40% placebo. No differences for RISA180
- Endoscopic response 47% RISA360 vs 47% RISA180 vs 22% placebo.
- Better endoscopic composite endpoints and inflammatory biomarkers were consistent with dose-response relationship.

Conclusion:

SC RISA is a safe and efficacious treatment for maintenance of remission in mod-severe CD.

