2023. DECIDER

RCT/thiopurine+/- allopurinol/IBD/

Clinical trial: Combination allopurinol-thiopurine versus standard thiopurine in patients with IBD escalating to immunomodulators (the DECIDER study)

Multicentre, randomised, placebo-controlled trial.
Adult patients with IBD who were commencing a thiopurine were randomized to thiopurine-alopurinol vs thiopurine-placebo. Patients received either 25mg mercaptopurine or 50 mg azathioprine for 2 weeks, if it was tolerated then they were randomized. Patients received 100mg of alopurinol or placebo+ doce adjustment depending on body weight and their allocated treatment group

Primary endpoint: Composite of symptomatic disease activity remission (HBI<5 or SCCAI<4) & Fcalprotectin <150ug/gr at w26.

Results: N=102 (Study terminated early due to slow recruitment)

- At week 26, higher number of patients on thiopurine-allopurinol 50% vs 35% thiopurine-placebo achieved the primary outcome, p=0.14
- Fewer patients stopped their allocated therapy due to adverse events 11% T-A vs 20% T-P, p=0.02
- Fewer patients experienced drug related adverse events 15% vs 44% T-A vs T-P respectively, p=0.002

Conclusion:
Thiopurine-alopurinol therapy is safe and mitigates thiopurine adverse effects, thus enhancing tolerability without compromising efficacy

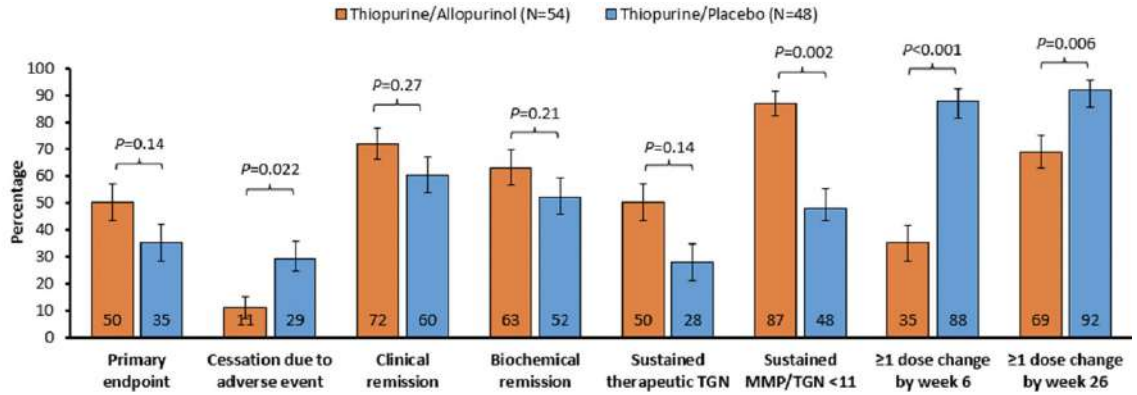

FIGURE 2 Percentage of patients achieving endpoints per treatment group by week 26 unless otherwise stated. Primary endpoint—faecal calprotectin (<150 μg/g) and corticosteroid-free clinical remission.

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