## Phase 3/management/CD/Maintain

Effect of tight control management on Crohn's disease(CALM): a multicentre, randomised, controlled phase 3 trial

Open-label, randomised controlled, phase 3 trial.

Patients with CD were randomized to tight control vs Clincal management (based on symptoms).

1<sup>st</sup> 8w prednisone induction+ escalated in stepwise: ADA +/-AZA.

<u>Primary endpoint</u>: mucosal healing (CDEIS<4) w48 <u>Secondary endpoints</u>: deep remission; biological remission; CDEIS<4; complete endoscopic remission; endoscopic response; steroid free remission, clinical remission.

## **Results:**

- Mucosal healing w48: 46% Tight control vs 30% clinical; p=0.01
- 2% tight control vs 20% clinical, needed rescue therapy.
- 76% tight control vs 74% clinical completed the study.

## **Conclusions:**

Timely escalation with an antiTNF on the basis of clinical symptoms and biomarkers in patients with early CD results in better clinical an endoscopic outcomes than symptom-driven decisions alone.



