

5ASA studies

1962

Steroids vs
sulphasalazine

RT / Combined oral+topical steroids vs sulphasalazine/ UC/ Induction of remission
Conclusion:
Combined systemic corticosteroids with prednisone and rectal hydrocortisone are better than sulphasalazine in achieving fast remission at week 2.

1962

Sulphasalazine

RT/ Sulphasalazine vs Salicylazosulphadimidine/ UC/ Induction
Conclusion:
**Sulphasalazine, but not salicylazosulphadimidine, was significantly better than placebo.
The optimum dose and duration of treatment have yet to be established.**

1973

Sulphasalazine

RT/ Sulphasalazine / UC/ Maintenance
Conclusion:
Maintenance treatment of ulcerative colitis with sulphasalazine should be continued indefinitely unless contraindicated by side effects.

1974

Salazopyrin

RT/ Salazopyrin/active CD/ Induction of remission
Conclusion:
Salazopyrin was not better than placebo in patients with CD with previous intestinal resection but it was better than placebo in those without previous surgery.

1979

Pred/Sulpha/
AZA

RCT/Prednisone, sulphasalazine, azathioprine or placebo/CD
Conclusion:
Prednisone & sulfasalazine are better than placebo inducing remission in CD but not AZA. Colonic CD was especially responsive to sulfasalazine & small bowel CD to prednisone. For patients in quiescent disease, none of the drug was superior to placebo preventing flare recurrence or postoperative recurrence.

5ASA studies

1980

5ASA/
sulphapyridin

RT / 5ASA vs sulphapyridin vs placebo / UC/ Induction of remission

Conclusion:

The results suggest that 5ASA is the active therapeutic moiety of sulphasalazine.

1987

Sulphasalazine

RT/ 5ASA vs placebo/ CD/ Induction

Conclusion:

5ASA at the dose used was not better than placebo in inducing clinical improvement in Crohn's disease

2000

5ASA Sup

RT/ 5ASA suppositories / UC proctitis/ Induction

Conclusion:

The results demonstrate that mesalamine suppositories are efficacious, well tolerated, and safe for the long-term maintenance of remission of ulcerative proctitis.

2000

5ASA postor

RT/ 5ASA/postoperative recurrence CD/ Recurrence

Conclusion:

Eighteen months of mesalamine, 4 g daily, did not significantly affect the postoperative course of Crohn's disease. Some relapse-preventing effect was found in patients with isolated small bowel disease.

2003

5ASA postor

RCT/5ASA/CD/ Postoperative recurrence

Conclusion:

A 4.0 g/day regimen of mesalazine does not offer a clinically significant advantage over a 2.4 g/day regimen in the prevention of post-operative endoscopic and clinical recurrence of CD at 1 year.

5ASA studies

2004

6MP/5ASA

RT / 5ASA vs 6MP / CD/ postoperative recurrence

Conclusion:

6-MP, 50 mg daily, was more effective than placebo at preventing postoperative recurrence of Crohn's disease and should be considered as a maintenance therapy after ileocolic resection.

2004

5ASA/AZA

RT/ 5ASA vs AZA/ CD/ Postoperative recurrence

Conclusion:

No difference was observed in the efficacy of AZA and mesalamine in preventing clinical and surgical relapses after conservative surgery.

2005

PINCE

RCT / 5ASA oral+ enema/ Mild-Mod UC/ Induction of remission

Conclusion:

In extensive mild-moderate active UC, enema + oral mesalazine superior than oral 5ASA alone.

2006

5ASA/ AZA

RCT/ 5ASA OD vs BD/active UC/ Induction of remission

Conclusion:

Azathioprine is significantly more effective than 5-aminosalicylic acid in inducing clinical and endoscopic remission and avoiding steroid requirement in the treatment of steroid dependent ulcerative colitis.

2007

ASCEND I

RCT/ 5ASA/ Mild-mod active UC/ Induction

Conclusion:

Preliminary evidence supporting the use of an initial 4.8 gr dose to treat moderate active UC.

This data were later confirmed in the ASCEND II (2007) and ASCEND III (2009) trials.

5ASA studies

2008

Balsalazide

RCT/ 5ASA/ Mild-mod active UC/ Induction

Conclusion:

Balsalazide disodium 1.1 gr tablets at 3.3 g twice daily dose are effective, well tolerated and better than placebo for improving signs and symptoms of mild-to-moderately active UC.

2009

5ASA MMX

RCT / 5ASA MMX vs asacol/ Mild-Mod UC/ Maintenance

Conclusion:

Once daily 5ASA-MMX is similarly effective with a comparable safety profile to Asacol administered twice daily, for the maintenance treatment of ulcerative colitis.

2010

5ASA/AZA
postor

RCT/ 5ASA OD vs BD/ Mild-mod left sided-UC/ Maintenance

Conclusion:

In this population of patients with postoperative CD at high risk of clinical recurrence, superiority for azathioprine versus mesalazine could not be demonstrated for therapeutic failure.

2011

5ASA/
budesonide

RCT/ 5ASA vs budesonide/ UC/ Induction

Conclusion:

Once-daily 3 g mesalazine administered as granules is numerically superior to 9 mg budesonide OD administered as capsules for achieving remission in mild-to-moderately active UC.

2012

PODIUM

RCT/ 5ASA OD vs BD/UC/ Maintenance

Conclusion:

Once daily slow-release mesalazine is similarly effective to the standard twice daily schedule in left-sided UC for the maintenance of remission in mild-to-moderate disease.

5ASA studies

2013

5ASA Sup

RCT/ 5ASA suppositories/ UC proctitis/ Induction

Conclusion:

The effectiveness of mesalazine suppositories in all types of UC patients with rectal inflammation was confirmed for the first time in a double-blind, placebo-controlled, parallel-group study

2013

MOTUS

RCT/ 5ASA OD vs BD/active UC/ Induction of remission

Conclusion:

Prolonged-release mesalazine OD 4 gr as effective and well tolerated as 2 gr BD for inducing remission in mild-to-moderately active UC.

2013

ADA/AZA/
5ASA

RCT / ADA vs AZA vs 5ASA/ CD/ Postoperative recurrence

Conclusion:

The administration of ADA after intestinal resective surgery was greatly effective in preventing endoscopic and clinical recurrence of CD.

2014

5ASA kids

RCT/ 5ASA high/low dose/ Mild-mod pediatric UC/ Induction

Conclusion:

Both low- and high-dose oral, delayed-release mesalamine doses were equally effective as short-term treatment of mild-mod active UC in children, without a specific benefit or risk to using either dose.

2018

5ASA enema

RCT/5ASA enema/ distal UC/ Induction

Conclusion:

Mesalazine foam enema was well-tolerated and was more effective than placebo in the treatment of patients with distal ulcerative colitis.

5ASA studies

2022

COMBOMESA

RCT/steroids +/- 5ASA/ ASUC

Conclusion:

Combination of mesalazine with steroids did not benefit hospitalized patients with ASUC more than steroids alone. An exploratory signal for a reduced need for biologics at 90 days in the mesalazine group merits further evaluation.

2023

5ASA MMX
kids

RCT/ 5ASA MMX low vs high dose/mild-moderate active UC/ Induction of remission

Conclusion:

The benefit-risk ratio of once-daily multimatrix mesalamine in paediatric patients was favourable and comparable with that reported in adults with mild-to-moderate UC.