

Perianal
disease

1987

Incision+/-
fistulotomy

RCT/ Incision +/- fistulotomy/ perianal CD/
Conclusion:

There were no differences between the two groups with regard to recurrent abscess/fistula, but the fistulotomy group had a statistically significantly higher prevalence of flatus incontinence.

1999

Infliximab

RCT/ IFX 5 mg/kg vs 10mg/kg vs placebo /fistulizing CD/ Induction
Conclusion:

Infliximab is an efficacious treatment for fistulas in patients with Crohn's disease.

2004

Infliximab

RCT/ IFX vs placebo/ fistulizing CD/ Maintenance
Conclusion:

Patients with fistulizing CD who have a response to induction therapy with infliximab have an increased likelihood of a sustained response over a 54-week period if infliximab treatment is continued every 8 weeks.

2003

Oral
Tacrolimus

RCT/Oral tacrolimus 0.2mg/kg/day vs placebo / fistulizing CD/ Induction
Conclusion:

Oral tacrolimus is effective for fistula improvement, but not fistula remission, in patients with perianal CD. Adverse events associated with tacrolimus can be managed by dose reduction.

2004

IFX +/-
ciprofloxacin

RCT/ Ciprofloxacin 500mg BD + IFX vs placebo+IFX /perianal CD/ Induction
Conclusion:

A combination of ciprofloxacin and infliximab tended to be more effective than infliximab alone.

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2007

Topical
tacrolimus

Exploratory RCT/topical tacrolimus 1 g BID vs placebo / perianal CD/ Induction

Conclusion:

These preliminary data suggest that topical tacrolimus is effective and safe in the treatment of perianal or anal ulcerating CD. This therapy is unlikely to be beneficial in fistulizing perianal CD.

2008

AST-120

RCT/ Oral spherical adsorptive carbon (AST-120) vs placebo /perianal CD/ Induction

Conclusion:

AST-120 is useful for the control of intractable anal fistulas in CD patients.

2010

Metronidazol
ointment

RCT/ Metronidazol 10% ointment (0.7g/8h) vs placebo ointment/ perianal CD/ Induction

Conclusion:

Metronidazole 10% ointment was not effective in the reduction of PDCAI score, but some secondary outcomes showed improvement suggestive of a treatment effect. It is well tolerated, with minimal adverse effects, and has potential as treatment for pain and discharge associated with perianal CD.

2014

FHAST-1

RCT phase 3/ Oral spherical adsorptive carbon (AST-120) vs placebo/perianal CD/ Induction

Conclusion:

In this largest placebo-controlled trial to date to evaluate the impact of a therapeutic agent on perianal CD, the efficacy of AST-120 could not be confirmed.

2014

ADAFI

RCT/ ADA v+/- ciprofloxacin 500mg BID /perianal CD/ Induction

Conclusion:

Combination therapy of ADA and ciprofloxacin is more effective than ADA monotherapy to achieve fistula closure in CD. However, after discontinuation of antibiotic therapy, the beneficial effect of initial coadministration is not maintained.

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2015

MSCs

RCT/bone marrow-derived mesenchymal stromal cells (MSCs) vs placebo / perianal CD/ Induction

Conclusion:

Local administration of allogeneic MSCs was not associated with severe adverse events in patients with perianal fistulizing Crohn's. Injection of MSCs appeared to promote healing of perianal fistulas

2016

ADMIRE-CD

RCT/ Expanded allogeneic adipose-derived mesenchymal stem cells (Cx601)vs placebo /pCD/ Induction

Conclusion:

Cx601 is an effective and safe treatment for complex perianal fistulas in patients with CD who did not respond to conventional or biological treatments, or both.

2020

PISA I

RCT/ seton vs anti-TNF vs surgical closure after 2 months under anti-TNF/perianal CD/Maintenance

Conclusion:

The results imply that chronic seton treatment should not be recommended as the sole treatment for perianal Crohn's fistulas.

2022

PISA-II

RCT/ 4-month anti-TNF& surgical closure or anti-TNF therapy for 1 y, after seton insertion/ perianal CD

Conclusion:

Short-term anti-TNF treatment combined with surgical closure induces long-term MRI healing more frequently than anti-TNF therapy in patients with perianal CD.

2022

Seton removal
+/- closure

RCT/ Seton removal +surgical closure vs seton removal alone /perianal CD/ Induction

Conclusion:

Seton removal alone seems to be no more effective than a secondary surgical step (in particular glue injection) in patients having fistulizing perianal CD controlled by an initial drainage combined with adalimumab. The results should be interpreted with caution.

Perianal
disease

RCT/Standard vedolizumab induction vs extra dose at week 10 / perianal CD/ Induction

Conclusion:

Sustained improvements in fistulizing CD were seen with both vedolizumab regimens. An additional dose at week 10 does not appear to alter treatment outcomes.

2022

ENTERPRISE

