

# Efficacy of vedolizumab in Crohn's disease

## Student EBM presentations

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# The Question

Clinical scenario: Mr. G comes to gastroenterology clinic having come previously and prescribed a TNF antagonist. Symptoms have persisted and feels unable to leave the house as has frequent and urgent bowel openings.

Vedolizumab is a NICE approved treatment for Crohn's.

The questions: Will Vedolizumab be a more effective treatment for Mr. G

<b>P</b>	Crohn's disease patient with previous TNF antagonist failure
<b>I</b>	Vedolizumab (300mg) IV
<b>C</b>	Placebo IV
<b>O</b>	Remission (Crohn's Disease Activity Index <150)

## The search

- PubMed search:
- ‘vedolizumab’  
AND
- ‘Crohn’s’  
AND
- ‘TNF’  
AND
- ‘Fail\*’

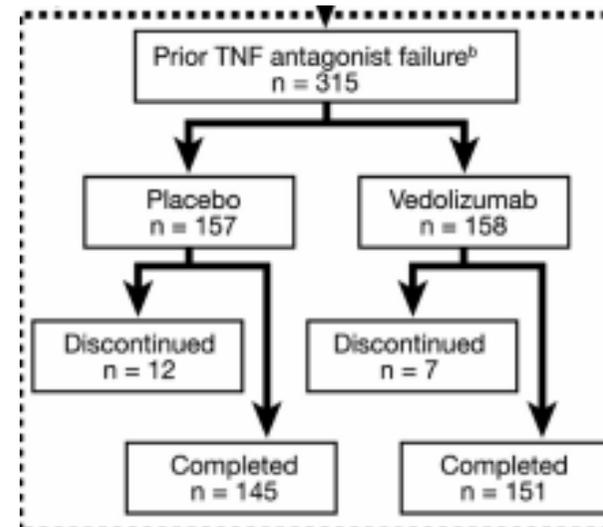
## The search results

- 9 results
- Only 1 RCT:
- “*Effects of Vedolizumab Induction Therapy for Patients With Crohn’s Disease in Whom Tumor Necrosis Factor Antagonist Treatment Failed” *Gastroenterology* 147, 618-627 (2014)*



# Study Appraisal

- Phase 3 Randomised Trial
- Placebo Controlled, Double Blind
- Multinational, Multicenter
- Patients from 107 site across all 5 major continents included based on clinical & endoscopic criteria
  - Patients w/ moderate-severe CD who failed previous TNF antagonist **randomly** assigned to vedolizumab or placebo by computer.
  - There was excellent follow-up (~5% dropout)
  - **Unbiased** outcome measurements (double blinded trial) and relevant (CDAI = gold standard diagnosis tool).



# The Results (interpretation of findings)

Risk	Remission (10 week)	No remission (10 week)
Placebo	<b>12.1%</b>	87.9%
Vedolizumab	<b>26.6%</b>	73.4%

- Absolute risk in MAb treated =  $26.6 - 12.1 = 14.5$
- Relative risk =  $26.6 / 12.1 = 2.2$  (95% CI = 1.3-3.6)
- P = 0.001

# The Implications

- Vedolizumab is more likely to allow remission of TNF antagonist-resistant Crohn's disease at 10 weeks compared to placebo.
- Clinically, it might be a useful therapy for moderate-severe TNF antagonist-resistant Crohn's disease, especially as there was no difference in adverse events.
- Complicating the clinical picture is cost-effectiveness, which is yet to be analysed.

