Duke Master of Biomedical Sciences

Efficacy and Safety of Dupilumab in Patients with Eosinophilic Gastritis with or without Eosinophilic Duodenitis

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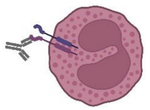
Goal

To evaluate the efficacy and safety of Dupilumab in reducing gastric and duodenal eosinophil counts and improving symptoms in patients with EoG with or without EoD.

Background

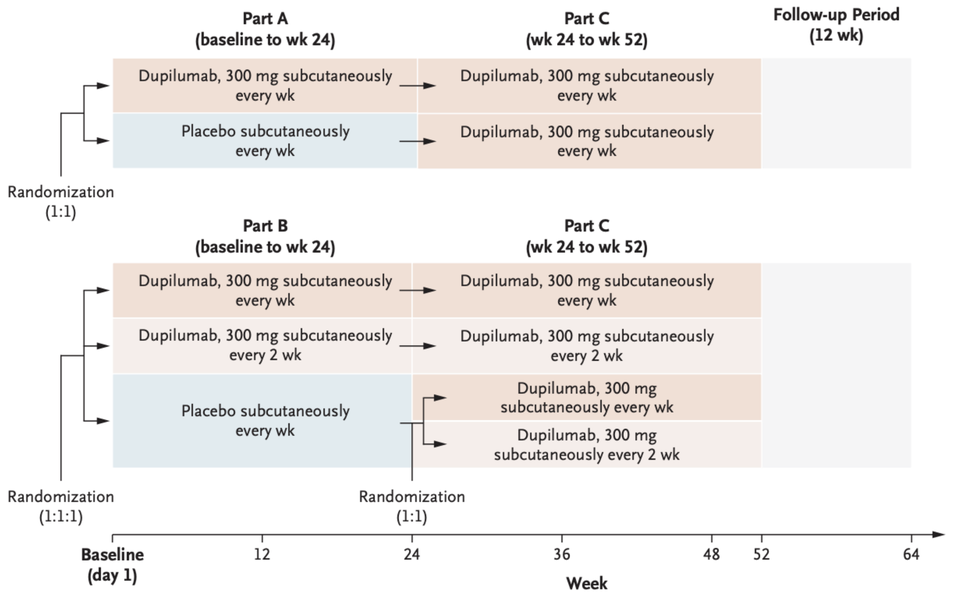
- Eosinophilic gastritis (EoG) and duodenitis (EoD) are chronic inflammatory disorders involving eosinophilic infiltration of the GI tract.
- Symptoms include abdominal pain, nausea, bloating, and diarrhea.
- No FDA-approved treatments currently exist for EoG/EoD.
- Dupilumab, a monoclonal antibody targeting IL-4 and IL-13 pathways, has shown promise in eosinophilic diseases (e.g., eosinophilic esophagitis).



Implementation

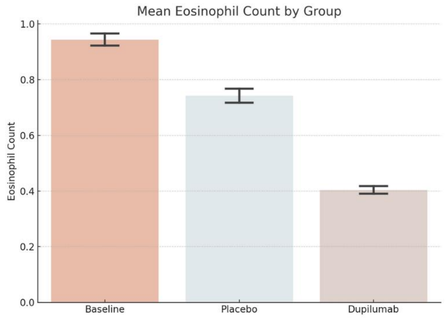
- Patients were randomized to receive Dupilumab weekly, every 2 weeks, or placebo for 24 weeks (Part A/B).
- All patients transitioned to open-label Dupilumab in Part C (24-52 weeks).
- Outcomes measured: histologic remission (≤ 6 eos/hpf), symptom scores, and adverse events.
- Data shown here reflects global study arms while Duke Health continues recruitment.

Main Findings

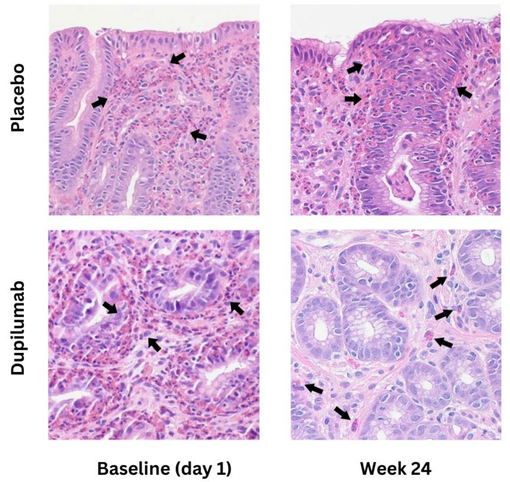


Proposed Study

(Methods adapted from Dellon et al. (2022))



Purpose: To visualize and compare the mean eosinophil counts between participants at baseline and after receiving either placebo or Dupilumab treatment after 24 weeks.
Expected Results: Dupilumab group is expected to show the most substantial reduction in eosinophil counts versus baseline or placebo.
Limitations: Participants receiving placebo in Part A or B are later transitioned to active Dupilumab in Part C. While ethically appropriate, this crossover design can make long-term comparisons between original treatment arms less clear.



Next Steps

- Continue recruitment at Duke Health under the ENGAGE protocol
- Collect histologic and patient-reported outcomes locally
- Analyze long-term safety data in Part C
- Evaluate correlations between eosinophil reduction and symptom relief

Future Implications

- Dupilumab could become the first FDA-approved therapy for EoG/EoD
- May provide a disease-modifying option for patients unresponsive to dietary changes or steroids
- Broader implications for eosinophilic GI disorders as a therapeutic class

References

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2. Hirano I, Dellon ES, Hamilton JD, et al. Efficacy of Dupilumab in a Phase 2 Randomized Trial of Adults With Active Eosinophilic Esophagitis. Gastroenterology. 2020;158(1):111-122.e10. doi:10.1053/j.gastro.2019.09.042
3. Sanofi. Dupixent® (dupilumab) meets all primary and key secondary endpoints in first-ever Phase 3 trial in eosinophilic gastritis and/or eosinophilic duodenitis. 2022. https://www.sanofi.com/en/media-room/press-releases/2022/2022-07-14-05-00-00-2479427
4. Regeneron P. A Trial to Learn if Dupilumab is Safe for and Helps Adult and Adolescent Participants with Eosinophilic Gastritis with or without Eosinophilic Duodenitis. 2025. https://clinicaltrials.ucsf.edu/trial/NCT05831176