Reappraisal of Comparison of the Efficacy and Safety of Biosimilar Adalimumab with Innovator Adalimumab in Ankylosing Spondylitis

Nitin Chintaman Gawari[1], Tanvi Naik[2*], Sujata Prakash Shingare[3], Yasir Hassan[4]

Keywords: Adalimumab injection, Ankylosing spondylitis, Efficacy.

Journal of The Association of Physicians of India (2026): 10.59556/japi.74.1565

Dear Editor,

We read with interest an article titled "Comparison of the Efficacy and Safety of Biosimilar Adalimumab Injection with Innovator Adalimumab in Subjects with Active Ankylosing Spondylitis," published in the Journal of the Association of Physicians of India.[1] We have the following comments to offer:

- While the introduction provides a solid pharmacological and socioeconomic context, there is an absence of a clearly stated hypothesis and primary outcomes. The rationale is regulatory rather than scientific, and the flow prematurely introduces methodological details that should appear later.[2]
- The Methods section is demonstrated very well. However, key methodological details are missing: justification for noninferiority margin and 2:1 allocation, incomplete blinding description, lack of missing data handling, and absence of recruitment timeline. These omissions limit full reproducibility and transparency, which are essential for validating noninferiority randomized controlled trials (RCTs).[3]
- While the Results section is statistically detailed and transparent about efficacy equivalence, it falls short on several parameters such as missing temporal and flow details (recruitment dates and attrition causes), lack of structured adverse event (AE) tables and graphical clarity, overuse of *p*-values instead of confidence intervals, incomplete analysis report, and missing data handling.[4]
- The unusually high response rates compared to global trials, the short 12-week duration, and sponsor involvement limit interpretability. Larger, longer, and independently funded multicenter studies across diverse populations are required to confirm long-term equivalence and safety.[5]

Orcid

Nitin Chintaman Gawari https://orcid.org/0009-0006-4241-8909
Tanvi Naik https://orcid.org/0009-0007-0155-9999
Sujata Prakash Shingare https://orcid.org/0009-0002-5260-364X
Yasir Hassan https://orcid.org/0009-0007-8917-9682

References

1. Chandrashekara S, Parida JR, Sonawale A, et al. Comparison of the efficacy and safety of biosimilar adalimumab injection with innovator adalimumab in subjects with active ankylosing spondylitis. J Assoc Physicians India 2025;73(9):e21–e27.
2. Schulz KF, Altman DG, Moher D, et al. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. J ClinEpidemiol 2010;63(8):834–840.
3. Piaggio G, Elbourne DR, Pocock SJ, et al. Reporting of noninferiority and equivalence randomized trials: extension of the CONSORT 2010 statement. JAMA 2012;308(24):2594–2604.
4. Bass AR, Stratton KR, Kumova OK, Rosenberg D (Eds). Evidence Review of the Adverse Effects of COVID-19 Vaccination and Intramuscular Vaccine Administration. National Academies Press; 2024.
5. Xu H, Li Z, Wu J, et al. IBI303, a biosimilar to adalimumab, for the treatment of patients with ankylosing spondylitis in China: a randomised, double-blind, phase 3 equivalence trial. Lancet Rheumatol 2019;1(1):e35–e43.

[1]Assistant Professor; [2]Junior Resident; [3]Assistant Professor; [4]Junior Resident, Department of Pharmacology, Dr. D. Y. Patil Medical College, Hospital and Research Centre, Pune, Maharashtra, India; *Corresponding Author

How to cite this article: Gawari NC, Naik T, Shingare SP, *et al.* Reappraisal of Comparison of the Efficacy and Safety of Biosimilar Adalimumab with Innovator Adalimumab in Ankylosing Spondylitis. J Assoc Physicians India 2026;74(8):92.