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CADTH Reference List

Switching From Reference to Biosimilar Etanercept for Patients with Plaque Psoriasis

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Summary of Abstracts

CADTH

Authors: Thyna Vu, Charlene Argáez

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Key Message

- Two randomized controlled trials were identified regarding the clinical effectiveness of switching from reference etanercept to biosimilar etanercept in adult or pediatric patients with plaque psoriasis.

Research Question

What is the clinical effectiveness of switching from reference to biosimilar etanercept in adult or pediatric patients with plaque psoriasis?

Methods

Literature Search Methods

A limited literature search was conducted by an information specialist on key resources including MEDLINE, Embase, the Cochrane Database of Systematic Reviews, the international HTA database, the websites of Canadian and major international health technology agencies, as well as a focused internet search. The search strategy comprised both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were etanercept and plaque psoriasis. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2016 and February 2, 2021. Internet links were provided, where available.

Selection Criteria and Summary Methods

One reviewer screened literature search results (titles and abstracts) and selected publications according to the inclusion criteria presented in Table 1. Full texts of study publications were not reviewed. The Overall Summary of Findings was based on information available in the abstracts of selected publications.

Results

Two randomized controlled trials were identified regarding the clinical effectiveness of switching from reference to biosimilar etanercept in adult or pediatric patients with plaque psoriasis.[1,2] No relevant health technology assessments, systematic reviews, or non-randomized studies were identified.

Additional references of potential interest that did not meet the inclusion criteria are provided in Appendix 1.

Table 1: Selection Criteria

Criteria	Description
Population	Patients (any age) with plaque psoriasis
Intervention	Switching from reference etanercept (i.e., Enbrel) to biosimilar etanercept (i.e., Erelzi, Brenzys)
Comparator	Continuous use of reference etanercept; pre/post switch comparisons
Outcomes	Effectiveness (e.g., change in disease severity or clinical response, disease activity, clinical remission, health-related quality of life) and safety (e.g., adverse events, withdrawal due to adverse event)
Study designs	Health technology assessments, systematic reviews, randomized controlled trials, non-randomized studies

Overall Summary of Findings

Two randomized controlled trials[1,2] analyzed data from the EGALITY study. Patients were randomly assigned to self-administer reference etanercept or biosimilar etanercept, and those that had at least a 50% improvement based on the Psoriasis Area and Severity Index (PASI 50) at week 12 were re-randomized to either continue using their initially assigned treatment, or to undergo 3 consecutive treatment switches until week 30. Following this, all patients remained on the last assigned treatment until week 52. Patients initially assigned to reference etanercept and patients assigned to biosimilar etanercept did not differ significantly in response rate at week 12.[2] Patients who switched treatments and patients who continued with the same treatment had similar treatment responses up to week 30 as measured by PASI 50, PASI 75, and PASI 90 response rates and percent change from baseline in PASI scores.[1] Incidence of treatment-emergent adverse events was also comparable across groups up to week 30[1] and week 52.[2] No patients tested positive for binding anti-drug antibodies.[1]

References

Health Technology Assessments

No literature identified.

Systematic Reviews and Meta-analyses

No literature identified.

Randomized Controlled Trials

1. Gerdes S, Thaci D, Griffiths CEM, et al. Multiple switches between GP2015, an etanercept biosimilar, with originator product do not impact efficacy, safety and immunogenicity in patients with chronic plaque-type psoriasis: 30-week results from the phase 3, confirmatory EGALITY study. *J Eur Acad Dermatol Venereol*. 2018 Mar;32(3):420-427. Medline

2. Griffiths CEM, Thaci D, Gerdes S, et al. The EGALITY study: a confirmatory, randomized, double-blind study comparing the efficacy, safety and immunogenicity of GP2015, a proposed etanercept biosimilar, vs. the originator product in patients with moderate-to-severe chronic plaque-type psoriasis. *Br J Dermatol*. 2017 Apr;176(4):928-938. Medline

Non-Randomized Studies

No literature identified.

Appendix 1: References of Potential Interest

Systematic Reviews and Meta-analyses

Alternative Comparator – Biosimilar Trials Compared to Pivotal Trials

3. Moots RJ, Curiale C, Petersel D, Rolland C, Jones H, Mysler E. Efficacy and safety outcomes for originator TNF inhibitors and biosimilars in rheumatoid arthritis and psoriasis trials: a systematic literature review. *Biodrugs*. 2018 Jun;32(3):193-199. Medline

Unclear Intervention and Unclear Population – Not Specific to Etanercept or Plaque Psoriasis

4. Jacobs I, Petersel D, Isakov L, Lula S, Lea Sewell K. Biosimilars for the treatment of chronic inflammatory diseases: a systematic review of published evidence. *Biodrugs*. 2016 01 Dec;30(6):525-570. Medline

Non-Randomized Studies

Alternative Intervention – Non-Switching

5. Egeberg A, Ottosen MB, Gniadecki R, et al. Safety, efficacy and drug survival of biologics and biosimilars for moderate-to-severe plaque psoriasis. *Br J Dermatol*. 2018 02;178(2):509-519. Medline

Unclear Population and Alternative Intervention – Not Specific to Plaque Psoriasis and Non-Switching

6. Pescitelli L, Lazzeri L, Di Cesare A, Tripo L, Ricceri F, Prignano F. Clinical experience with the etanercept biosimilar SB4 in psoriatic patients. *Int J Clin Pharm*. 2019 Feb;41(1):9-12. Medline

Alternative Population – Inflammatory or Rheumatoid Arthritis

7. Jaworski J, Matucci-Cerinic M, Schulze-Koops H, et al. Switch from reference etanercept to SDZ ETN, an etanercept biosimilar, does not impact efficacy, safety, and immunogenicity of etanercept in patients with moderate-to-severe rheumatoid arthritis: 48-week results from the phase III, randomized, double-blind EQUIRA study. *Arthritis Res Ther*. 2019 05 28;21(1):130. Medline

8. Madenidou AV, Jeffries A, Varughese S, et al. Switching patients with inflammatory arthritis from etanercept (Enbrel) to the biosimilar drug, SB4 (Benepali): a single-centre retrospective observational study in the UK and a review of the literature. *Mediterr J Rheumatol*. 2019;30(Supplement1):69-75. Medline

Alternative Population and Alternative Intervention – Arthritis and Non-Switching

9. Codreanu C, Popescu CC, Mogosan C, et al. Efficacy and safety of original and biosimilar etanercept (SB4) in active rheumatoid arthritis - a comparison in a real-world national cohort: original and biosimilar etanercept in RA. *Biologicals*. 2019 November;62:27-32. Medline

Review Articles

Unclear Population – Not Specific to Plaque Psoriasis

10. Deeks ED. GP2015: An etanercept biosimilar. *Biodrugs*. 2017 Dec;31(6):555-558. Medline

11. Moots R, Azevedo V, Coindreau JL, et al. Switching between reference biologics and biosimilars for the treatment of rheumatology, gastroenterology, and dermatology inflammatory conditions: considerations for the clinician. *Curr Rheumatol Rep*. 2017 01 Jun;19 (6):37. Medline

Alternative Population – Arthritis

12. Lyseng-Williamson KA, McKeage K. SB4 (Benepali; an etanercept biosimilar): a profile of its use. *Drugs Ther Perspect*. 2018 01 Feb;34(2):50-61.

13. Cantini F, Benucci M. Focus on biosimilar etanercept - bioequivalence and interchangeability. *Biologics*. 2018;12:87-95. Medline

14. Burness CB, Duggan ST. Etanercept (SB4): a review in autoimmune inflammatory diseases. *Biodrugs*. 2016 Aug;30(4):371-378. Medline

Additional References

15. Fisher A, Kim JD, Dormuth CR. Rapid monitoring of health services utilization following a shift in coverage from brand name to biosimilar drugs in British Columbia-an interim report. *Pharmacoepidemiol Drug Saf*. 2020 Jul;29(7):803-810. Medline