

CADTH Reference List

Switching From Reference to Biosimilar Insulin Lispro for Patients with Diabetes Mellitus (Type 1 or 2)

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Key Message

- One randomized controlled trial was identified regarding the clinical effectiveness of switching from reference to biosimilar insulin lispro in adult or pediatric patients with diabetes mellitus (type 1 or 2).

Research Question

What is the clinical effectiveness of switching from reference to biosimilar insulin lispro in adult or pediatric patients with diabetes mellitus (type 1 or 2)?

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 concept was insulin lispro biosimilars. No filters were applied to limit the retrieval by study type. Conference abstracts were excluded from the search results. 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 9, 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

One randomized controlled trial was identified regarding the clinical effectiveness of switching from reference to biosimilar insulin lispro in adult or pediatric patients with diabetes mellitus (type 1 or 2).¹ 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 diabetes mellitus (type 1 or 2)
Intervention	Switching from reference insulin lispro (i.e., Humalog) to biosimilar insulin lispro (i.e., Admelog)
Comparator	Continuous use of reference insulin lispro; pre/post switch comparisons
Outcomes	Effectiveness (e.g., change in disease severity, disease complications, 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

One crossover randomized controlled trial¹ assessed the safety of switching between reference insulin lispro and biosimilar insulin lispro administered by continuous subcutaneous insulin infusion pumps for patients with type 1 diabetes mellitus. Patients were randomized to receive the reference or biosimilar for 4 weeks, then switched to the other treatment for 4 weeks.¹ The number of patients reporting at least 1 infusion set occlusion (ISO) was low in both treatment groups, and the estimated difference in ISO risk was not significantly different between groups.¹ The event rate of hypoglycemia and the percentage of patients who experienced any treatment-emergent adverse events were also similar between treatment groups.¹

References

Health Technology Assessments

No literature identified.

Systematic Reviews and Meta-analyses

No literature identified.

Randomized Controlled Trials

Crossover Study Assessing Insulin Lispro Administered by Continuous Subcutaneous Insulin Infusion Pump

1. Thrasher J, Surks H, Nowotny I, et al. Safety of insulin lispro and a biosimilar insulin lispro when administered through an insulin pump. *J Diabetes Sci Technol*. 2018 05;12(3):680-686. [Medline](#)

Non-Randomized Studies

No literature identified.

Appendix 1: References of Potential Interest

Systematic Reviews and Meta-analyses

Alternative Intervention – Not Specific to Insulin Lispro and Not Switching

2. Ampudia-Blasco FJ. Biosimilars and novel insulins. *Am J Ther.* 2020 Jan/Feb;27(1):e52-e61. [Medline](#)
3. Tieu C, Lucas EJ, DePaola M, Rosman L, Alexander GC. Efficacy and safety of biosimilar insulins compared to their reference products: a systematic review. *PLoS ONE.* 2018;13(4):e0195012. [Medline](#)
4. Yamada T, Kamata R, Ishinohachi K, et al. Biosimilar vs originator insulins: systematic review and meta-analysis. *Diabetes Obes Metab.* 2018 07;20(7):1787-1792. [Medline](#)

Randomized Controlled Trials

Alternative Intervention – Not Switching

5. Mayorov AY, Mosikian AA, Alpenidze DN, et al. Efficacy and safety of GP40021 insulin lispro biphasic compared with Humalog Mix 25 in type 2 diabetes mellitus patients. *J Comp Eff Res.* 2021 Jan;10(1):55-66. [Medline](#)
6. Derwahl KM, Bailey TS, Wernicke-Panten K, Ping L, Pierre S. Efficacy and safety of biosimilar SAR342434 insulin lispro in adults with type 2 diabetes, also using insulin glargine: SORELLA 2 Study. *Diabetes Technol Ther.* 2018 01;20(1):49-58. [Medline](#)
7. Home P, Derwahl KM, Ziemien M, et al. Anti-insulin antibodies and adverse events with biosimilar insulin lispro compared with humalog insulin lispro in people with diabetes. *Diabetes Technol Ther.* 2018 02;20(2):160-170. [Medline](#)
8. Garg SK, Wernicke-Panten K, Rojeski M, Pierre S, Kirchhein Y, Jedynasty K. Efficacy and safety of biosimilar SAR342434 insulin lispro in adults with type 1 diabetes also using insulin glargine-SORELLA 1 Study. *Diabetes Technol Ther.* 2017 09;19(9):516-526. [Medline](#)

Alternative Outcomes – Pharmacokinetics and Pharmacodynamics

9. Kapitza C, Nowotny I, Lehmann A, et al. Similar pharmacokinetics and pharmacodynamics of rapid-acting insulin lispro products SAR342434 and US- and EU-approved Humalog in subjects with type 1 diabetes. *Diabetes Obes Metab.* 2017 05;19(5):622-627. [Medline](#)

Review Articles

Alternative Intervention – Not Switching

10. Hu J, Wang M, Zhao Y. SAR342434 - an insulin biosimilar for the treatment of type II diabetes. *Expert Opin Biol Ther.* 2018 11;18(11):1107-1112. [Medline](#)

Alternative Intervention – Not Specific to Insulin Lispro and Not Switching

11. White J, Goldman J. Biosimilar and follow-on insulin: the ins, outs, and interchangeability. *J Pharm Technol.* 2019 35(1): 25–35. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6313268/>