Sotrovimab for the Treatment of COVID-19

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Questions or requests for information about this report can be directed to requests@cadth.ca
Key Messages

- There is a lack of published peer-reviewed evidence regarding the clinical effectiveness of sotrovimab for the treatment of individuals with coronavirus disease 2019 (COVID-19).
- Results from an ongoing trial, which are expected later this year, should provide decision-makers with an increased understanding of the potential role of sotrovimab for the treatment of individuals with COVID-19.

Context and Policy Issues

Sotrovimab (also known as VIR-7831) is a human monoclonal antibody that binds the spike protein of severe acute respiratory syndrome coronavirus 2, the virus that causes COVID-19.1 Engineered from an antibody isolated from a patient who recovered from severe acute respiratory syndrome in 2003,1 this investigational therapeutic received an Emergency Use Authorization by the FDA in May 20212 and was authorized under Interim Order by Health Canada in July 2021.3 These regulatory decisions were based on preliminary results of the COVID-19 Monoclonal antibody Efficacy Trial — Intent to Care Early (COMET-ICE).2-4 The objective of the current report is to summarize the available evidence regarding the clinical effectiveness of sotrovimab for the treatment of COVID-19.

Research Question

What is the clinical effectiveness of sotrovimab for the treatment of coronavirus disease 2019 (COVID-19)?

Methods

Literature Search Methods

A limited literature search was conducted by an information specialist on key resources including MEDLINE, Embase, PubMed, 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 was comprised of both controlled vocabulary, such as the National Library of Medicine’s MeSH (Medical Subject Headings), and keywords. The main search concept was sotrovimab. No filters were applied to limit retrieval by publication type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2019 and August 30, 2021.

Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.
Table 1: Selection Criteria

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Description</th>
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<tbody>
<tr>
<td>Population</td>
<td>Individuals with confirmed COVID-19</td>
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<tr>
<td>Intervention</td>
<td>Sotrovimab (alone or in combination with other therapies)</td>
</tr>
<tr>
<td>Comparator</td>
<td>No treatment; placebo; other active treatments (e.g., casirivimab-imdevimab)</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Clinical effectiveness (e.g., mortality, length of hospital stay, severity of clinical symptoms, viral load, safety [e.g., adverse events])</td>
</tr>
<tr>
<td>Study designs</td>
<td>Health technology assessments, systematic reviews, RCTs, and non-randomized studies</td>
</tr>
</tbody>
</table>

COVID-19 = coronavirus disease 2019; RCTs = randomized controlled trials.

Exclusion Criteria

Articles were excluded if they did not meet the selection criteria outlined in Table 1, they were duplicate publications, or were published prior to 2019.

Summary of Evidence

Quantity of Research Available

A total of 16 citations were identified in the literature search. Following screening of titles and abstracts, 13 citations were excluded and 3 potentially relevant reports from the electronic search were retrieved for full-text review. One potentially relevant publication was retrieved from the grey literature search for full-text review. Of these potentially relevant articles, 4 publications were excluded for various reasons, and no publications met the inclusion criteria and were included in this report. Appendix 1 presents the PRISMA flow chart of the study selection. Additional references of potential interest are provided in Appendix 2.

Summary of Findings

Clinical Effectiveness of Sotrovimab for the Treatment of COVID-19

No relevant evidence regarding the clinical effectiveness of sotrovimab for the treatment of individuals with confirmed COVID-19 was identified; therefore, no summary can be provided.
Conclusions and Implications for Decision- or Policy-Making

No relevant literature was identified regarding the clinical effectiveness of sotrovimab for the treatment of individuals with confirmed COVID-19. While results from a preplanned interim analysis\(^6\) from an ongoing randomized controlled trial\(^4\) investigating the effectiveness of sotrovimab (i.e., VIR-7831) versus placebo for the early treatment of non-hospitalized COVID-19 patients are available in a preprint, these results are preliminary and have not been peer-reviewed, and thus were not eligible for inclusion in this review. The final results of this clinical trial,\(^4\) as well as any subsequent studies, should provide decision-makers with some clarity with respect to the potential role of sotrovimab for the treatment of COVID-19.
References


Appendix 1: Selection of Included Studies

516 citations identified from electronic literature search and screened

13 citations excluded

3 potentially relevant articles retrieved for scrutiny (full text, if available)

1 potentially relevant report retrieved from other sources (grey literature, handsearch)

4 potentially relevant reports

4 reports excluded:
- irrelevant study design (review articles, editorials, non-peer-reviewed preliminary reports) (4)

0 reports included in review
Appendix 2: References of Potential Interest

Previous CADTH Reports

Review Articles

Regulatory Documents and News Releases
Fact sheet for healthcare providers emergency use authorization (EUA) of sotrovimab. Silver Spring (MD): U.S. Food and Drug Administration: 2021: https://www.fda.gov/media/149534/download