INPLASY PROTOCOL

To cite: Moza et al. Outcome of newborns in case of SARS-CoV-2 vertical infection. Inplasy protocol 2022120093. doi:

10.37766/inplasy2022.12.0093

Received: 22 December 2022

Published: 23 December 2022

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Support: None.

Review Stage at time of this submission: Data analysis.

Conflicts of interest: None declared. Outcome of newborns in case of SARS-CoV-2 vertical infection

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Review question / Objective: To identify the types and examine the range of available evidence of vertical transmission of SARS-CoV-2 from mother to newborn. To clarify the key concepts and criteria for diagnosis of SARS-CoV-2 vertical infection in neonates. To summarize the existing evidence and advance the awareness on SARS-CoV-2 vertical infection in pregnancy.

Background: Severe Acute Respiratory Syndrome Virus 2 (SARS-CoV-2), the virus that causes 2019 coronavirus disease (COVID-19), has been isolated from various tissues and body fluids, including the placenta, amniotic fluid, and umbilical cord of newborns. In the last few years, much scientific effort has been directed towards studying SARS-CoV-2, focusing on the different features of the virus, such as its structure and mechanisms of action. Moreover, much focus has been on developing accurate diagnostic tools and various drugs or vaccines to treat COVID-19.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 23 December 2022 and was last updated on 23 December 2022 (registration number INPLASY2022120093).

INTRODUCTION

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Rationale: Although numerous articles report vertical transmission, this topic is still controversial because case-cohort studies still need to report clear evidence, and only some reviews have used standard classification systems for diagnosis. Standard diagnostic criteria should be used when facing the possibility of vertical transmission.

METHODS

Strategy of data synthesis: The search was conducted on PubMed/MEDLINE and Google Scholar. The following terms were used: ('covid*' OR 'SARS-CoV-2*') AND ('vertical transmission' OR 'in-utero transmission' OR 'congenital transmission' OR 'placental infection'). The search period was Jan. 01 2020 – Nov. 01 2022. Reference lists of all identified sources were searched for additional sources.

Eligibility criteria: No limit or restriction was imposed in regard to the type of study: all types of evidence are to be taken into consideratioldentified publications comprised the following categories: systematic reviews, case reports and case studies, articles that describe vertical transmission at a molecular level, casecohort studies, case-control studies, longitudinal cohort studies, cross-sectional studies, descriptive studies and studies based on surveys.

Systematic reviews were not further analyzed to avoid the risk of entering a case multiple times.

Source of evidence screening and selection: The studies were identified by

two independent researchers. All articles were screened for duplicates and abstracts of all potentially relevant papers were individually examined for suitability. Disagreements were resolved by consensus or a third (senior) researcher settled the disagreement. The following inclusion criteria were applied: (1) application of the standard criteria (the WHO or Shah's criteria) in the attempt to diagnose vertical transmission; (2) delivery after 20 weeks of gestation; (3) delivery using strict infection control and prevention practices; (4) mother-neonate separation at least for 24h after birth.

Data management: Data were synthesized into an Excel spreadsheet. Descriptive quantitative statistics were performed. A data charting form was established based on WHO and Shah's criteria. Quality assessment was conducted based on the criteria stated by Murad et al. (Murad MH, Sultan S, Haffar S, Bazerbachi F. Methodological quality and synthesis of case series and case reports. BMJ Evid Based Med. 2018 Apr:23(2):60-63. doi: 10.1136/bmjebm-2017-110853.) for the case or case series reports. For the cohort studies, quality was assessed based on the PICO framework and Newcastle-Ottawa Scale Coding Manual (Gierisch JM, Beadles C, Shapiro A, et al. Health Disparities in **Quality Indicators of Healthcare Among** Adults with Mental Illness [Internet]. Washington (DC): Department of Veterans Affairs (US); 2014 Oct. APPENDIX B, NEWCASTLE-OTTAWA SCALE CODING MANUAL FOR COHORT STUDIES. Available from: https:// www.ncbi.nlm.nih.gov/books/ NBK299087/).

Reporting results / Analysis of the evidence: The studies were grouped according to the charting form. The cases with confirmed or possible vertical transmission were stratified by the neonatal outcome. For livebirth neonates, descriptive quantitative statistics were determined.

Presentation of the results: For quality assessment, stacked bar graph was

employed. For all the other results, tables were used to synthesize the results.

Language restriction: Only publications written in English were selected.

Country(ies) involved: Romania.

Keywords: SARS-CoV-2; COVID-19; vertical transmission; congenital transmission; placenta; amniotic fluid; umbilical cord.

Dissemination plans: Publication of a research article in an open access medical journal.

Contributions of each author:

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