INPLASY

INPLASY2023120117

doi: 10.37766/inplasy2023.12.0117

Received: 30 December 2023

Published: 30 December 2023

Corresponding author:
Stefania Ronzoni

stefania.ronzoni@sunnybrook.ca

Author Affiliation:
Sunnybrook Health Sciences Centre.

Systematic Review and Meta-Analysis of Randomized Controlled Trials Assessing the Effect of Different Dental Disease Treatments on Preterm Birth Outcomes

Thomas, C[1]; Ahmed, S[2]; D'Souza, R[3]; Berghella, V[4]; Brignardello, R[5]; El-Rabanny, M[6]; Devion, C[7]; Ronzoni, S[8].

ADMINISTRATIVE INFORMATION

Support - NA.

Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY2023120117

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 30 December 2023 and was last updated on 30 December 2023.

INTRODUCTION

Review question / Objective Does the treatment of dental disease during pregnancy reduce the risk of preterm birth?

Rationale Evidence suggests that dental disease is associated with preterm birth. There is some evidence from randomized controlled trials suggesting that treatment of some dental conditions may reduce the risk of preterm birth. This study aims to systematically review and meta-analyze evidence on the impact of various dental disease treatments on preterm birth and other obstetric adverse events.

Condition being studied The condition being studied is dental diseases in pregnancy. This includes but is not limited to dental caries, gingivitis, gum disease/infection/inflammation/disorder, periodontitis, periodontal disease/infection/inflammation/disorder, oral bacterial infection.

METHODS

Search strategy Eligible studies will be identified by a predefined search strategy of the electronic databases. The search strategy will be conducted with assistance from a medical information specialist. The search will be conducted in accordance with Peer Reviewed Electronic Search Strategies (PRESS) guidelines (2015). The search strategy will include terms related to Dental diseases such as dental caries; gingivitis; gum disease/infection/inflammation/disorder; periodontitis periodontal disease/infection/inflammation/disorder; pulpitis, pericoronitis, oral bacterial infection; pregnancy granuloma; pregnancy gingivitis, dental disease treatments

such as oral hygiene, dental cleanings, scaling, root planning, chlorhexidine, mouthwash, root canal treatment, cavity fillings, periodontal treatments, extraction, incision and drainage, debridement, pregnancy and randomized controlled trials. In addition, reference lists of included studies and systematic reviews on the topic will be reviewed to ensure no articles are missed through the original search strategy. The search will be re-run just before the final analyses and further studies retrieved for inclusion.

Participant or population Pregnant patients with any dental disease (including but not limited to dental caries, gingivitis, gum disease, periodontitis, pulpitis, pericoronitis, oral bacterial infection, pregnancy granuloma, pregnancy gingivitis), at any stage of pregnancy.

Intervention Dental disease treatments, including but not limited to: oral hygiene, dental cleanings, scaling, root planning, mouthwash, chlorhexidine, extraction, incision and draining, debridement, root canal treatment, cavity fillings, periodontal treatments, etc.

Comparator No dental treatment during pregnancy. Note that depending on the study results, we may also compare one intervention to another, e.g.,a scaling and root planing with chlorhexidine mouthwash vs. scaling and root planing without chlorhexidine mouthwash – this will depend on the data availability.

Study designs to be included We will include all randomized controlled trials that compared dental interventions among each other or vs no interventions.

Eligibility criteria We will apply no year or language restrictions. Animal studies will be excluded.

Information sources The literature search will be conducted for MEDLINE, EMBASE, Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, Web of Science, Global Index of Medicus. We will also review Google Scholar, Prospero, Clinicaltrials.gov, International Clinical Trials Registry Platform, International Standards RCT number. to identify trials published in non-indexed journals (and to identify ongoing trials for the next iteration of the living systematic review). Reference lists of included studies and systematic reviews on the topic will be screened for articles that might have been missed through the original search.

Main outcome(s) Preterm birth (< 37 weeks' gestation or as reported by study authors).

Additional outcome(s) Any additional pregnancy-related outcomes will be included. This will depend on what data is available. This will include but is not to the following:
a. fetal and neonatal outcomes: perinatal loss (miscarriages, stillbirths and neonatal deaths), congenital malformations, fetal growth concerns (small for gestational age, fetal growth restriction, low birthweight or birthweight, as reported and defined in original studies), other neonatal complications such as severe neonatal morbidity, neonatal intensive care unit admission, Apgar scores, abnormal cord gases, neonatal infectious morbidity or any other neonatal outcomes as reported);
b. maternal outcomes such as surgical and anesthetic complications, maternal morbidity and mortality, patient-satisfaction outcomes, as well as health care resource/utilization and cost data, if reported.

Data management Covidence software will be used to manage articles, including removing duplicates and managing initial title/abstract screening. Two reviewers will independently review the title and abstracts of all articles pulled from the search. These will be reviewed against pre-specified criteria for inclusion/exclusion. Following this, two reviewers will independently and in duplicate review the full articles for inclusion, again using pre-specified criteria. Any discrepancies will be agreed upon through discussion and consensus and may involve a third senior researcher reviewer. Non-English language publications will be translated into English by team members/ translators fluent in the respective languages.

Quality assessment / Risk of bias analysis The final set of studies included will be evaluated for risk of bias using the Cochrane Risk Assessment Tool by two reviewers under the guidance of a senior investigator. In addition, studies will be assessed for trustworthiness using the Research Integrity Assessment (RIA) tool and by searching the Retraction Watch Database for all included studies.

Strategy of data synthesis We will provide a detailed description of the included studies, structured around the type of intervention, target population characteristics, type of outcome and intervention content. We will provide summaries of intervention effects for each study by calculating risk ratios (for dichotomous outcomes) or mean differences (for continuous outcomes). Statistical

heterogeneity between the studies will be assessed using both the χ2 test and the I2 statistic. We will pool results across studies using random-effects meta-analyses, weighting the studies using the inverse variance method for continuous outcomes and the Mantel-Haenzel or inverse variance methods for dichotomous outcomes depending on whether prevalence is low or not. We will use the most optimal effect estimate abstracted from each of the studies. We will do a narrative synthesis of the findings at the outcome level when meta-analysis is not possible. For each outcome, we will rate the certainty of the evidence (COE) as high, moderate, low, or very low using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach. To summarize all the information, we will create GRADE Summary of Findings tables in which we will present both relative and absolute estimates of effect and their associated certainty of evidence.

Subgroup analysis Subgroup analysis will depend on the data available from the studies retrieved. If data allows, subgroup analysis may be performed by type of dental disease and type of intervention. If data allows, dental diseases will be classified by (1) inflammatory conditions (if data allows, this can be further sub-divide by periodontitis, gingivitis, pulpitis, pericoronitis, other) vs (2) non-inflammatory conditions (includes carries and others).

Sensitivity analysis Sensitivity analysis is dependent on the data available and may include high versus low resource settings; risk of study bias; study publication year; and any other similar parameters based on data availability. We will conduct sensitivity analyses excluding studies with unadjusted effect estimates. We will also assess evidence of publication bias using visual inspection of funnel plots with 95% and 99.7% control limits, where more than 10 studies were included in the analysis.

Language restriction None.

Country(ies) involved Canada, USA.

Keywords pregnancy; dental disease; periodontal disease; gingivitis; dental disease treatment; periodontal treatment; oral hygiene; preterm birth; prematurity; early gestational age; systematic.

Dissemination plans This study will be presented at national and international conferences and published in a General medical, Obstetrics & Gynaecology-related academic journal.

Contributions of each author

Author 1 - Ronzoni Stefania.
Email: stefania.ronzoni@sunnybrook.ca
Author 2 - Shakil Ahmed.
Email: ahmes112@mcmaster.ca
Author 3 - Rohan D'Souza.
Email: rohan@mcmaster.ca
Author 4 - Vincenzo Berghella.
Email: vincenzo.berghella@jefferson.edu
Author 5 - Romina Brignardello.
Email: brignarr@mcmaster.ca
Author 6 - Mohamed El-Rabbany.
Email: morabbany@gmail.com
Author 7 - Catherine Devion.
Email: catherine.devion@sunnybrook.ca
Author 8 - Camille Thomas.
Email: camille.thomas@mail.utoronto.ca