

# INPLASY PROTOCOL

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**Corresponding author:**  
João Canellas

drcanellas@icloud.com

**Author Affiliation:**  
Rio de Janeiro State University

**Support:** CAPES (Brazil)

**Review Stage at time of this submission:** The review has not yet started.

**Conflicts of interest:**  
None declared.

## What is the best antibiotic protocol for preventing infection after orthognathic surgery? A protocol for systematic review and network meta-analysis

Soares, B<sup>1</sup>; Drugos, L<sup>2</sup>; Medeiros, PJ<sup>3</sup>; Canellas, JV<sup>4</sup>.

**Review question / Objective:** What is the most appropriate regimen for antibiotic prophylaxis to prevent surgical site infection after orthognathic surgery?

**Condition being studied:** Surgical site infection after orthognathic surgery.

**Information sources:** We will search the following electronic bibliographic databases: EMBASE, PubMed, Cochrane Central Register of Controlled Trials (CENTRAL), LILACS database, Scopus database and Web of Science database. There will be no language restrictions and no year restriction. We will use the PICOS strategy for the research question construction and evidence search. The reference lists of the articles identified will be cross-checked. Furthermore, and studies from the 'grey literature' will be screened through the following trial registry platform: ClinicalTrials.gov (<http://www.clinicaltrials.gov>). A manual search will be done in the relevant journals of Dentistry. We will contact study correspondent authors to solve any uncertainties.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 06 May 2020 and was last updated on 06 May 2020 (registration number INPLASY202050023).

### INTRODUCTION

**Review question / Objective:** What is the most appropriate regimen for antibiotic prophylaxis to prevent surgical site infection after orthognathic surgery?

**Rationale:** It is well known that infection after orthognathic surgery is a factor that influences postoperative recovery and the degree of satisfaction. Several antibiotic regimens have already been tested and instituted. The scientific literature have

reported. However, there is no systematic review that combines randomized clinical trials using direct and indirect evidence to compare all these protocols.

**Condition being studied:** Surgical site infection after orthognathic surgery.

## METHODS

**Search strategy:** The search strategy will be published with the final paper as a supplementary material.

**Participant or population:** This study will include healthy humans who have undergone orthognathic surgery to correct dentofacial deformity. No restrictions regarding gender, ethnicity, or age were applied.

**Intervention:** The use of systemic antibiotic to prevent surgical site infection after orthognathic surgery.

**Comparator:** No systemic antibiotic or a different regimen.

**Study designs to be included:** We will include only randomized clinical trials.

**Eligibility criteria:** Studies will be selected according to the PICOS criteria (Participant, intervention, comparator, outcomes, and study design) outlined in the referred sections. Patients included in the primary studies must be healthy patients e.g. (by American Society of Anesthesiologists - ASA I or II definition).

**Information sources:** We will search the following electronic bibliographic databases: EMBASE, PubMed, Cochrane Central Register of Controlled Trials (CENTRAL), LILACS database, Scopus database and Web of Science database. There will be no language restrictions and no year restriction. We will use the PICOS strategy for the research question construction and evidence search. The reference lists of the articles identified will be cross-checked. Furthermore, and studies from the 'grey literature' will be screened through the following trial

registry platform: [ClinicalTrials.gov](http://www.clinicaltrials.gov) (<http://www.clinicaltrials.gov>). A manual search will be done in the relevant journals of Dentistry. We will contact study correspondent authors to solve any uncertainties.

**Main outcome(s):** Surgical site infection.

**Additional outcome(s):** Side effects of antibiotics - adverse events.

**Data management:** The references will be imported into Endnote X9 software (Thompson Reuters, Philadelphia, PA, USA) where duplicates will be automatically removed. All analyses will be performed using the software R version 3.6.2 or updated Mac OS X computer system. The packages "meta", "metafor", "metasens", "dosresmeta", "netmeta", "rmeta", "pcnetmeta" will be used. These packages are available from the Comprehensive R Archive Network (CRAN).

**Quality assessment / Risk of bias analysis:** Two review authors will independently assess the risk of bias. We will use the Cochrane tool for assessing risk of bias. Sequence generation - Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups. Allocation concealment - Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen in advance of, or during, enrollment. Blinding of participants, personnel and outcome assessors - Describe all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received.

**Strategy of data synthesis:** A pairwise meta-analysis for direct evidence and a network meta-analysis for direct and indirect evidence of eligible comparisons will be accomplished. We will provide a quantitative and narrative synthesis. We will provide summaries of intervention effects for each study by calculating

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standardized mean differences or mean differences. We will pool the results using a fixed or random-effects meta-analysis. Heterogeneity will be assessed using both the  $\chi^2$  test and the  $I^2$  statistic. We will consider an  $I^2$  value greater than 50% indicative of substantial heterogeneity. In addition to the heterogeneity assessment using the  $I^2$  statistic, the assumption of transitivity and similarity based on clinical and methodological characteristics will be assessed. The inconsistency will be explored using the Net Heat Plot. We will also assess evidence of publication bias.

**Subgroup analysis:** None.

**Sensibility analysis:** None.

**Language:** There is no language restriction.

**Country(ies) involved:** Brazil.

**Other relevant information:** None.

**Keywords:** Antibiotic prophylaxis; orthognathic surgery; systematic review; network meta-analysis.

**Dissemination plans:** The results of this systematic review will be disseminated through peer reviewed journals.

**Contributions of each author:**

**Author 1 - Brunna Soares** - This author drafted the protocol. She will be responsible for preparing the search methodology and the selection criteria. The author will select included studies and accomplish the risks of bias analysis.

**Author 2 - Luciana Drugos** - The author will select included studies and accomplish the risks of bias analysis.

**Author 3 - Paulo José Medeiros** - The author will read, supervise, provided feedback, and approved the final manuscript.

**Author 4 - João Vitor Canellas** - The author contributed to the development of the present protocol. He will read, supervise, provided feedback, provide statistical expertise, and approve the final manuscript. The author will solve any disagreement in selection process.