INPLASY PROTOCOL

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

Conflicts of interest:
None.

Effect of CO2 laser for the management of primary otosclerosis: A protocol for systematic review and meta-analysis

Zhang, YY[1]; Wang, JS[2]; Zhang, SH[3]; Liu, GF[4]; Zheng, PJ[5].

Review question / Objective: **Is CO2 laser (COL) effective and safety for the management of patients with primary otosclerosis (PO)?**
Condition being studied: **Primary otosclerosis; CO2 laser.**
Information sources: **We will search following electronic databases from inception to the present: PubMed, EMBASE, The Cochrane Library, Web of Science, PsycINFO, Cumulative Index to Nursing and Allied Health Literature, Allied and Complementary Medicine Database, Chinese Biomedical Literature Database, VIP, WANGFANG, and China National Knowledge Infrastructure. We will not apply any limitations of language and publication status. The detailed search strategy sample of PubMed will be presented. We will also build similar search strategies for other electronic databases. We will also search grey literature to avoid missing any potential studies, including conference abstracts, ongoing trials from clinical trial registry, and reference lists of associated reviews.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 18 April 2020 and was last updated on 18 April 2020 (registration number INPLASY202040110).

INTRODUCTION

Review question / Objective: **Is CO2 laser (COL) effective and safety for the management of patients with primary otosclerosis (PO)?**

Condition being studied: **Primary otosclerosis; CO2 laser**

METHODS

Participant or population: **We will include any participants who were diagnosed as PO. There will be no limitations of race, gender, country, and disease duration.**

Intervention: **In the experimental group, all participants underwent COT therapy in this**

study. COT combined with other modalities will be excluded.

Comparator: In the control group, the comparators could be any management, except any forms of COT.

Study designs to be included: Only randomized controlled trials (RCTs) on investigating the effect and safety of COL for the treatment of PO will be included in this study.

Eligibility criteria: Only RCTs on investigating the effect and safety of COL for the treatment of PO will be included in this study without limitations of language and publication status.

Information sources: We will search following electronic databases from inception to the present: PubMed, EMBASE, The Cochrane Library, Web of Science, PsycINFO, Cumulative Index to Nursing and Allied Health Literature, Allied and Complementary Medicine Database, Chinese Biomedical Literature Database, VIP, WANGFANG, and China National Knowledge Infrastructure. We will not apply any limitations of language and publication status. The detailed search strategy sample of PubMed will be presented. We will also build similar search strategies for other electronic databases. We will also search grey literature to avoid missing any potential studies, including conference abstracts, ongoing trials from clinical trial registry, and reference lists of associated reviews.

Main outcome(s): Primary outcome measure is hearing gain, as assessed by pure-tone audiometry, or any other relevant tools. Secondary outcome measurements are tinnitus severity, as measured by Tinnitus Functional Index or other indexes; incidence of intraoperative (bleeding and fractured footplate); health-related quality of life, as identified by Health-Related Quality-of-Life 14-Item Measure or other scales; and other morbidities (such as vomiting, vertigo, sensorineural hearing loss, and facial nerve paralysis).

Data management: Data will be collected by two researchers independently with a pre-designed data collection form. It include article information, such as first author, publication time, and location; patient information, such as sample size, race, sex, age, and types of PO; study design, such as detailed information of randomization, blind and allocation; intervention and controls, such as types of therapies, duration, and frequency; outcomes, such as primary and secondary outcome measurements; safety; and sources of funding. If the data were unclear or missing in original study, we will contact corresponding authors to inquire it. If entered RCTs include multiple groups, we will only extract data from groups, which is consistent with the objectives of this study. Any discrepancies between two researchers will be solved through team discussion with the help of a third researcher.

Quality assessment / Risk of bias analysis: Risk of bias will be checked by two independent researchers using Cochrane risk of bias tool for RCTs. It covers 7 items, and each item is classified as low, unclear and high risk of bias. In case of divergences between two researchers, a third researcher will be involved to help resolve them by discussion.

Strategy of data synthesis: For continuous values, we will express them as mean difference with the same unit or standardized mean difference with different unit and 95% confidence intervals (CIs). For dichotomous values, risk ratio and 95% CIs will be used to calculate them. I^2 statistic test will be used for heterogeneity identification. It is interpreted as $I^2 \leq 50\%$ indicating minor heterogeneity, and we will use a fixed-effects model; while $I^2 > 50\%$ showing obvious heterogeneity, and we will utilize a random-effects model. A meta-analysis will be carried out if heterogeneity is minor. Otherwise, we will conduct a subgroup analysis to explore the possible factors that may result in obvious heterogeneity. Additionally, we will also carry out a descriptive summary and narrative synthesis.

Subgroup analysis: We will conduct subgroup analysis according to the different characteristics of study or patient, different interventions or controls, and different outcome measurements.

Sensibility analysis: If necessary, we will also perform sensitivity analysis to check the robustness of pooled outcome results by removing low quality studies.

Country(ies) involved: China.

Keywords: Primary otosclerosis; CO2 laser; effect; safety.