# INPLASY PROTOCOL

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## A systematic review and meta-analysis of the effect of photodynamic therapy for treatment of oral mucositis

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**Review question / Objective:** Is photodynamic therapy effective in preventing and / or treating lesions of oral mucositis induced by radio and / or chemotherapy?

**Condition being studied:** Oral mucositis; oral mucositis induced by radiotherapy ; oral mucositis induced by chemotherapy and photodynamic therapy.

Information sources: PubMed, Scopus, Web of Science, Science Direct, SciELO, Embase and Cochrane library databases were searched. In addition, a manual searched was performed in the main journals with photodynamic therapy as scope.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 02 March 2021 and was last updated on 02 March 2021 (registration number INPLASY202130006).

### INTRODUCTION

**Review question / Objective:** Is photodynamic therapy effective in preventing and / or treating lesions of oral mucositis induced by radio and / or chemotherapy? **Rationale:** Oral mucositis (OM) is one of the most serious and frequent complications in oncological patients that are undergoing chemotherapy and / or radiotherapy treatment protocols. The prevalence of OM varies from 33.87% to 100% of cases. Until now, there is neither consensus on the level of evidence presented by the studies

nor agreement on what the best therapeutic option for treat OM. In the last decade, great emphasis has been given to photobiomodulation as an effective modality in preventing OM and reducing its symptoms. Studies demonstrated that laser shows angiogenic ability and antiinflammatory and analgesic action. As the oral cavity has a lot of microorganism, which can infect the OM lesions, the use of photodynamic therapy in the treatment of OM may be promising. Thus, we expected to conduct a systematic review to evaluate the significant results of photodynamic therapy in the OM treatment.

Condition being studied: Oral mucositis; oral mucositis induced by radiotherapy ; oral mucositis induced by chemotherapy and photodynamic therapy.

### **METHODS**

Search strategy: Two independent examiners conducted an electronic search in the PubMed, Scopus, Web of Science, Science Direct, SciELO, Embase and Cochrane library databases. Prior to the start of the systematic review, a kappa calibration was performed and the classification score between the examiners was 0.92, showing an "almost perfect" agreement (p <0.01) between them. The following search terms were ((photodynamic therapy OR Photochemotherapy)) AND (oral mucositis OR Stomatitis). Data were extracted from selected papers. Studies were analyzed and discussed. Any possibility of disagreement during the process was solved before proceeding to the next steps being third reviewer consulted. The literature review was carried out from February to May 2020. The records obtained were exported to Mendeley Reference Manager Software® to detect and exclude duplicates.

Participant or population: Only human clinical trials were included in this present systematic review. The patients must have diagnostic of OM, induced by radiotherapy or chemotherapy. Intervention: Only photodynamic therapy or photodynamic therapy associate with more one other treatment.

**Comparator:** Other treatments without photodynamic therapy.

Study designs to be included: Only human clinical trials were included in the present systematic review.

Eligibility criteria: The inclusion criteria for this systematic review were: human clinical trials, studies that directly or in association with other therapies evaluated the effect of photodynamic therapy on oral mucositis lesions and articles written in English. No restrictions were used on specifying the type of photosensitizer or type of light used.

Information sources: PubMed, Scopus, Web of Science, Science Direct, SciELO, Embase and Cochrane library databases were searched. In addition, a manual searched was performed in the main journals with photodynamic therapy as scope.

Main outcome(s): The main outcome was the healing time. The effect measures used in the present systematic review and metaanalysis was the mean-difference. The random effect model was used to evaluate this variable.

Quality assessment / Risk of bias analysis: For the quality assessment the Delphi list criteria was used. For evaluate the risk of bias, the RoB 2 tool was used.

Strategy of data synthesis: The informations were extracted for the elegible studies and put on the table. The following information were: first author name, publication year, type of photosensitizer, wave-length, irradiation time, sample size, control group and the main outcomes.

Subgroup analysis: The subgroup analysis was not performed.

**Sensitivity analysis:** The sensitivity analysis was not performed.

Language: Only articles written in English were added in the present systematic review.

Country(ies) involved: Brazil.

Keywords: Oral mucositis; photodynamic therapy; systematic and meta-analysis review.

### **Contributions of each author:**

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