INPLASY PROTOCOL

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None declared.

Management of medication related of osteonecrosis of the jaw (MRONJ) using human amniotic membrane: a systematic review and meta-analysis

Sacco, R[1].

Review question / Objective: **Is the human amniotic membrane a viable and successful treatment option for patients affected by MRONJ?**
Condition being studied: **Medication-related osteonecrosis of the jaw (MRONJ) is a rare and severe adverse drug reaction, consisting of progressive bone destruction in the maxillofacial region of patients. MRONJ pathophysiology is not completely elucidated. There are several suggested hypothesis that could explain its unique localisation to the jaws: Inflammation or infection, micro-trauma, altered bone remodelling or over suppression of bone resorption, angiogenesis inhibition, soft tissue BPs toxicity, peculiar biofilm of the oral cavity, terminal vascularisation of the mandible, suppression of immunity, or Vitamin D deficiency. The treatment of MRONJ is generally difficult and the optimal therapy strategy is still to be established. Hence new effort should be made to implement the management of the disease.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 04 March 2023 and was last updated on 04 March 2023 (registration number INPLASY202330010).

INTRODUCTION

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Condition being studied: **Medication-related osteonecrosis of the jaw (MRONJ) is a rare and severe adverse drug reaction, consisting of progressive bone destruction in the maxillofacial region of patients. MRONJ pathophysiology is not completely elucidated. There are several suggested hypothesis that could explain its unique localisation to the jaws: Inflammation or infection, micro-trauma, altered bone remodelling or over suppression of bone**

resorption, angiogenesis inhibition, soft tissue BPs toxicity, peculiar biofilm of the oral cavity, terminal vascularisation of the mandible, suppression of immunity, or Vitamin D deficiency. The treatment of MRONJ is generally difficult and the optimal therapy strategy is still to be established. Hence new effort should be made to implement the management of the disease.

METHODS

Participant or population: Any (no limits of age) patients affected with MRONJ.

Intervention: Any MRONJ treatment (Surgical and Non-surgical treatments) using human amniotic membrane.

Comparator: No applicable.

Study designs to be included: Randomized controlled trials, Case-controlled trials, Cohort studies (prospective and or retrospective), Case series and Case report.

Eligibility criteria: All studies involving patients who developed MRONJ taken antiresorptive and/or antiangiogenic therapy. No restriction of age, gender or ethnic origin was applied. There was also no restriction on the minimum number of patients included in the studies.

Information sources: To reduce the chances of missing any data, the search method will be carried out in on different databases: "PubMed, MEDLINE, EMBASE, and CINAHL". The search will be conducted to locate multi-language papers.

Main outcome(s): Evaluate the success rate (complete healing) of treating MRONJ cases with human amniotic membrane and its level of evidence.

Quality assessment / Risk of bias analysis: Some (n=2) review authors will assess the risk of bias of the included study according the Cochrane Handbook for Systematic Reviews of Interventions.

For case-control studies we will use the Risk of Bias in Non-randomised Studies - of Interventions (ROBINS-I).
The authors will use the consensus-based clinical case reporting guidelines development (CARE checklist) for case report.

Strategy of data synthesis: Following a comprehensive screening to determine eligible studies, all selected papers will be carefully read to identify study and patient characteristics. To assess primary and secondary outcomes, data will be extracted from each study and analysed. Where pooling of results is inappropriate, the results will be reported as narrative descriptions using a detailed commentary.

Subgroup analysis: All participants will be included in the final analysis. If data permits, a subgroup analysis will be included in this review. Sensibility analysis: If sufficient data are extracted, a sensitivity analysis will be conducted to check the stability of the outcome results by excluding low methodological quality or high risk of bias studies.

Sensitivity analysis: If sufficient data are extracted, a sensitivity analysis will be conducted to ascertain the validity of the outcome selected with the potential exclusion of the low quality studies.

Language restriction: No language restrictions will be applied.

Country(ies) involved: UK.

Keywords: MRONJ, management, human amniotic therapy, bisphosphonate.

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