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Mesenchymal stem cell therapy vesus placebo for knee osteoarthritis in adult patients: A protocol for a systematic review

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202490071

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 17 September 2024 and was last updated on 17 September 2024.

INTRODUCTION

Review question / Objective The aim of this systematic review is to compare the therapy with mesenchymal stem cells and placebo in terms of efficacy and side effects for the knee osteoarthritis. To this end, the proposed systematic review will address the following question: Is the therapy with mesenchymal stem cells effective in relieving the symptoms of knee osteoarthritis in adult patients?

Rationale The intra articular infiltration of autologous mesenchymal stem cells is an emerging treatment for the symptoms of knee osteoarthritis. At this time, some progress has been made in elucidating its effectiveness, through many randomized clinical trials. However, no systematic review synthesizing the results was found, which motivates the formulation of this study.

Condition being studied The knee osteoarthritis is a common progressive condition that affects the knee joint causing, mainly, chronic pain and stiffness. The severity of the symptoms can vary in a wide range from a minor discomfort to the inability to walk. The actual understanding of its pathophysiology points to the wear of the articular cartilage and chronic inflammation as the main features of the disease.

METHODS

Search strategy Search in the PubMed with the query: ("knee osteoarthritis"[Title/Abstract] AND "stem cell"[Title/Abstract]) AND (clinicaltrial[Filter]).

Participant or population Adults diagnosed with osteoarthritis of the knee.

Intervention Infiltration of autologous mesenchymal stem cells, obtained from any site, in the affected knee.

Comparator Infiltration of saline solution in the knee.

Study designs to be included Only randomized controlled trials will be eligible.

Eligibility criteria Will be eligible randomized controlled trials of adult patients with medically diagnosed knee osteoarthritis comparing the administration of mesenchymal stem cells on the affected knee versus the administration of normal saline.The study must report as an outcome measure the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and the pain visual analog scale (VAS). Will not be eligible studies that associate any other intervention with the infiltration of mesenchymal stem cells, such as hyaluronic acid, fresh frozen plasma, among others.

Information sources MEDLINE.

Main outcome(s) Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC); pain visual analog scale (VAS).

Quality assessment / Risk of bias analysis The risk of bias of the individual studies will be assessed using the revised Cochrane risk-of-bias tool for randomized trials (RoB 2). The quality of evidence of the outcomes measures will be assessed with the current Grading of Recommendations, Assessment, Development and Evaluation (GRADE) Working Group approach.

Strategy of data synthesis The data will be analyzed with R 4.4.0 and metafor package 4.6-0 using both fixed and random effects models. The results will be presented as a standardized mean difference and heterogeneity will be assessed using Cochran's Q test and expressed as a I^2 statistic.

Subgroup analysis None at the time.

Sensitivity analysis The authors will review their decision of including or excluding articles from the study and report the reason and potential impact of their decision.

Country(ies) involved Brazil.

Keywords Mesenchymal Stem Cell Transplantation; Osteoarthritis; Knee; Pain.

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