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The Effects of Stem Cell Therapy for Patients with Diabetic Foot: An Overview of Systematic Reviews and Meta-Analyses

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ADMINISTRATIVE INFORMATION

Support - The study was funded by the National Natural Science Foundation of China.

Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202380037

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 09 August 2023 and was last updated on 09 August 2023.

INTRODUCTION

Review question / Objective Stem Cell Therapy is a potential complementary treatment for Diabetic Foot. This overview systematically summarizes and evaluates the existing evidence of Stem Cell TherapyTC in the treatment of DF.

Condition being studied The studies were eligible if they adhered to the following criteria: (1) publication in English or Chinese language, (2) only controlled trials involving human subjects, (3) recruit patients with diabetic foot and divide them into a local treatment group using stem cells or a control group (with no treatment or placebo), and (4) report of one or more outcomes regarding the healing of the ulcers or wound, amputation, new vessels, ABI, TcPO2, pain-free walking distance, and restpain.

METHODS

Participant or population DF.

Intervention Stem cells.

Comparator CT.

Study designs to be included SRs/MAs of RCTs.

Eligibility criteria The studies were eligible if they adhered to the following criteria: (1) publication in English or Chinese language, (2) only controlled trials involving human subjects, (3) recruit patients with diabetic foot and divide them into a local treatment group using stem cells or a control group (with no treatment or placebo), and (4) report of one or more outcomes regarding the healing of the ulcers or wound, amputation, new vessels,

ABI, TcPO2, pain-free walking distance, and restpain.

Information sources We systematically searched Cochrane, Embase, PubMed, Web of Science, China National Knowledge Infrastructure, and WanFang databases for all related literature works. Te fnal search was updated on April 10, 2022, using the terms (("stem cell*"[Title/Abstract] OR "bone marrow"[Title/Abstract] OR "progenitor cell*"[Title/Abstract] OR "lipoaspirate cell*"[Title/Abstract] OR "mononuclear cell*"[Title/Abstract]) AND ("diabetic*"[Title/Abstract] OR "diabetic*"[Title/ Abstract])) AND ("wound"[Title/Abstract] OR "ulcer"[Title/Abstract] OR "foot"[Title/Abstract] OR "ischemia"[Title/Abstract] OR "ischaemia"[Title/ Abstract]. Te publication language was restricted to Chinese and English. Te original and review articles were manually identifed, and the references that met the requirements were included in this study.

Main outcome(s) Of the ulcers or wound, amputation, new vessels, ABI, TcPO2, pain-free walking distance, and restpain.

Quality assessment / Risk of bias analysis
2.6. Assessment of Methodological Quality
2.6.1. Estimate of Methodological Quality The methodological quality of the included SRs/MAs was assessed by the Assessment System for Evaluating Methodological Quality 2 (AMSTAR-2) [21]. Seven (2, 4, 7, 9, 11, 13, and 15) of the 16 items in the tool were critical areas.
2.6.2. Assessment of Risk of Bias The Risk of Bias in Systematic Review (ROBIS) [22] scale was used in this overview to evaluate the risk of bias of the inclusion of SRs/MAs. The scale was used to assess the overall risk of bias in the inclusion of SRs/MAs in three stages.
2.6.3. Assessment of Reporting Quality The quality of each SR/MA report of the included SRs/MAs was evaluated by the list of PRISMA [23] which consisted of 27 items focusing on the reporting methods and results that were incorporated into the SRs/MAs.
2.6.4. Assessment of Quality of Evidence The quality of evidence for each SR/MA outcome was evaluated by the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) [24], according to which, five aspects will lead to the degradation of evidence quality, including limitations, inconsistencies, indirectness, imprecision, and publication bias.

Strategy of data synthesis NA.

Subgroup analysis NA.

Sensitivity analysis NA.

Country(ies) involved China.

Keywords Diabetic foot, Stem cell,Meta-analysis.
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