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Mesenchymal stem cells injections in traumatology and orthopaedics: common practice or still a promising area with many uncertainties?

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Abstract

Purpose To assess research directions of the Mesenchymal stem cells (MSCs) injections in traumatology and orthopaedics.

Methods The study monitored the protocols of randomised controlled trials (RCTs) and systematic reviews (SRs) investigating mesenchymal stem cell (MSC) injections for various traumatological and orthopaedic conditions. Relevant RCT protocols were identified through searches of ClinicalTrials.gov, International Clinical Trials Registry Platform, EU Clinical Trials Register databases for RCTs and SRs were obtained from PROSPERO. The databases were searched from their inception to December 2023.

Results A total of 449 clinical trials were identified. At the time of the study, 159 (35.4%) trials had been completed, and only 56 (12.5%) had published results in peer-reviewed journals. Data on clinical trial completion were normally distributed ($p=0.145$). The duration for trial completion was 40.6 ± 26.5 months (range: 1 to 153 months). The most commonly investigated indications for MSCs injections were osteoarthritis of the hip and knee (37.6%) and spinal cord injuries (10.5%). The most frequent sources of MSCs were bone marrow (26.5%), adipose-derived (20.5%) and umbilical cord (15.4%). Reported MSCs concentrations varied widely, ranging from 0.5×10^6 to 9.7×10^8 cells. The most frequently used concentrations were 1×10^7 (8.2%), 2×10^7 (8.0%), 5×10^7 (5.8%), and 10×10^7 (5.8%) cells, while 59 other dosing schemes were each used in fewer than 1% of trials. Furthermore, 55.5% of protocols did not specify the cell concentration. A search in PROSPERO identified 114 systematic review protocols. By the time of the study, 32 studies (28.10%) had been completed, with the results of 30 (26.32%) published in peer-reviewed journals.

Conclusion MSC injections represent a growing area of research in traumatology and orthopaedics. However, the results of only a small proportion of clinical trials and systematic reviews are published in peer-reviewed journals, which most likely does not allow practitioners to form a full judgement on the efficacy and safety of this treatment.

Keywords Orthobiologics, Injection therapy, Regenerative medicine, Medicinal signaling cells

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Introduction

In recent decades, there has been a significant growth of interest regarding orthobiologic treatment modalities for a variety of pathological conditions. Among these, the use of platelet-rich plasma (PRP) and mesenchymal stem cells (MSCs) has emerged as one of the most popular practices. MSCs include a heterogeneous population of cells isolated from a range of different tissues [1]. There are numerous studies most often confirming the efficiency of PRP in the treatment of various musculoskeletal system pathologies [2–6]. There is considerably less available evidence for MSCs, although it has been shown to be effective in treating tendinopathies, osteoarthritis, discogenic pain and nonunion fractures in a number of systematic reviews and meta-analyses [7–10].

There are still no open access data in the largest academic research databases about the effectiveness of MSCs in the group of elite athletes, who traditionally make the highest demands on the results of treatment [11–15]. At the same time, there are reports in mass media that some of them resort to treatment with MSCs as a miracle remedy that solve their health problems [16–19].

Some of the key challenges associated with MSCs include the relatively limited duration since their introduction into clinical practice, considerably heterogeneity in injection protocols, the diverse sources of their origin and significant variability in patient populations enrolled in clinical trials. In this regard, it is of high interest to analyse the available clinical research protocols that evaluated the efficacy of using MSCs in traumatology and orthopaedics. This approach could contribute to the objectivization of available data regarding this promising orthobiological method allowing practitioners to choose the most relevant treatment protocols with realistic, evidence-based expectations.

Aim of the study: to assess research directions of the MSCs injections in traumatology and orthopaedics by analysing the results of clinical trials and systematic reviews protocols, identifying their completion and publication status.

Methods

The study monitored the protocols of randomised controlled trials (RCTs) and systematic reviews (SRs) investigating mesenchymal stem cell (MSC) injections for various traumatological and orthopaedic conditions. Relevant RCT protocols were identified through searches of ClinicalTrials.gov, International Clinical Trials Registry Platform, EU Clinical Trials Register databases for RCTs, and systematic reviews were analysed in PROSPERO. The databases were searched from their inception to December 2023.

The keywords used to search in all databases were identified after preliminary literature searches. The keywords used were Mesenchymal Stem Cell*, Mesenchymal Stromal Cell*, Stem cell therap*, Adipose derived stem cell, Allogeneic Cell-based therap*, Hematopoietic Stem Cell, Bone Marrow Mesenchymal Stem Cell*, Traumatic injury*, Traumatology, Trauma, Trauma Injur*, Orthopedic Disorder, Orthopedic Injur*, Sports Injur*, Athletic Injur*. The search results obtained from each protocol database were recorded in an Excel spreadsheet and reviewed by the three researchers. The title, participants, mesenchymal cell type used, dosage, country of conduction, traumatological and orthopaedic condition, study start date and current completion and publishing status were analysed for each trial protocol found. Disagreements or discrepancies in the findings were managed by the senior investigator if necessary.

A ranking of the five pathologies for which the MSCs injections were most commonly used was generated, as well as a ranking of the ten countries in which the studies were most often conducted.

Local ethics committee approval was not required since publicly available data were utilized. The study was conducted according to the Helsinki declaration. The data were obtained from open access sources, therefore no informed consent for study participation was necessary.

All statistical analyses were performed using Python (version 3.11.9) with the scipy.stats package. The Kolmogorov-Smirnov test was used to assess the normality of trial completion data. A significance threshold of $p < 0.05$ was applied for all statistical tests.

Results

Clinical trials

A total of 449 clinical trials were identified, the first of which was conducted in 1995. At the time of the study, 159 (35.4%) trials had been completed, and only 56 (12.5%) had published results in peer-reviewed journals. Clinical trial protocols were distributed as follows: the majority were registered on ClinicalTrials.gov (62.8%), followed by the International Clinical Trials Registry Platform at 24.72%, and ClinicalTrialsRegister.eu at 12.47%. An analysis of the number of ongoing trials showed an increase in the number of trials over the ten-year time intervals. Between 1995 and 2005, only 6 trials were initiated. In contrast, 202 trials were registered from 2006 to 2016, and this number rose to 241 from 2017 to 2024 (Fig. 1).

Data on clinical trial completion were distributed normally ($p = 0.145$). The duration for trial completion was 40.6 ± 26.5 months (range: 1 to 153 months). Notably, at the time of data collection, 290 trials remained incomplete.

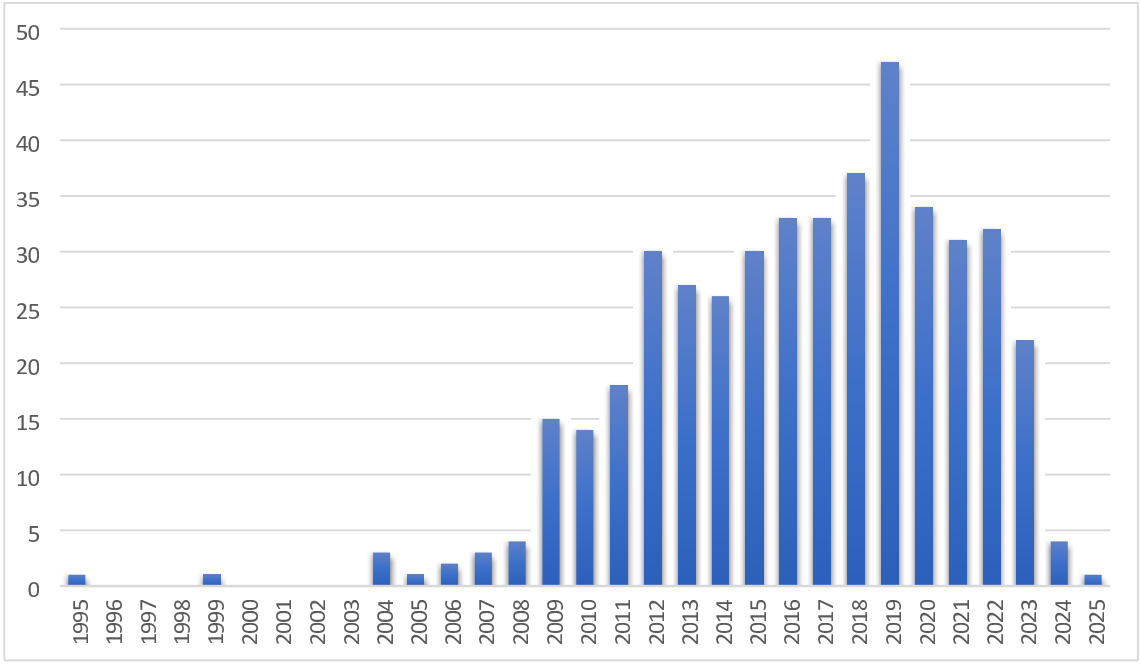

Fig. 1 Distribution of trials for MSCs use in traumatology and orthopaedics by year of study initiation

Table 1 The five most common orthopaedic and traumatological conditions for which mesenchymal stem cells are utilized in clinical trials

Condition	Number of trials	Completed	Published
Osteoarthritis	169 (37.6%)	64 (37.9%)	18 (10.7%)
Spinal cord injuries	47 (10.5%)	19 (40.4%)	6 (12.8%)
Cartilage defect	35 (7.8%)	9 (25.7%)	4 (11.4%)
Fractures	35 (7.8%)	13 (37.1%)	2 (5.7%)
Tendinopathy	7 (1.6%)	1 (14.3%)	0

Table 2 Ten countries that have published the highest number of clinical research trials on the use of mesenchymal stem cells in traumatological pathologies

Country	Number of trials	Completed	Published
China	69 (15.37%)	10 (14.49%)	4 (5.80%)
USA	51 (11.36%)	20 (39.22%)	8 (16.69%)
Spain	50 (11.14)	22 (44.00%)	8 (16.00%)
Iran	36 (8.02%)	12 (33.33%)	5 (13.89%)
South Korea	33 (7.35%)	19 (57.58%)	5 (15.15%)
Italy	15 (3.34%)	2 (13.33%)	0
France	10 (2.23%)	4 (40.00%)	1 (10.00%)
India	10 (2.23%)	1 (10.00%)	1 (10.00%)
Taiwan	10 (2.23%)	5 (50.00%)	1 (10.00%)
Brasil	10 (2.23%)	2 (20.00%)	0

The most commonly investigated indications for MSCs injections were Osteoarthritis of the hip and knee joints (37.6%), Spinal Cord Injuries (10.5%), Cartilage defect and Fractures of various localisations (7.8%). At the same time, the highest percentage in terms of trial completion was in those trials that investigated the efficacy of MSCs in the treatment of Spinal Cord Injuries (40.4%), Osteoarthritis of the hip and knee joints (37.9%) and Fractures (37.1%). It is important to note that the percentage of published studies did not exceed 13% of the total number of studies conducted for any of the conditions (Table 1).

The distribution of countries with ongoing clinical trials is noteworthy: China (69), the USA (51), and Spain (50) had the highest number of registered trials. Meanwhile, Spain (22), the USA (20), and South Korea (19) reported the highest number of completed trials (Table 2).

The most frequent sources of MSCs were BM-MSCs (Bone marrow mesenchymal stem cells): 26.5%; AD-MSCs (Adipose delivered mesenchymal stem cells): 20.5% and UC-MSCs (Umbilicord cord mesenchymal stem cells): 15.4%. The other sources were used considerably less frequently.

Reported MSCs concentrations varied widely, ranging from 0.5×10^6 to 9.7×10^8 cells. The most frequently used concentrations were 1×10^7 (8.2%), 2×10^7 (8.0%), 5×10^7 (5.8%), and 10×10^7 (5.8%) cells, while 59 other dosing schemes were each used in fewer than 1% of trials. Notably, 249 (55.5%) of protocols did not specify the cell concentration. Information on specific traumatological and orthopaedic conditions, sources of MSCs used and concentrations in the corresponding trial protocols is presented in Table 3.

The risk of bias analysis demonstrated that all clinical trial protocols included in this review had a moderate risk of bias (Table 4).

Table 3 The sources and dosages used in the treatment of the five most common orthopaedic and traumatological conditions for which mesenchymal stem cells are utilized in clinical trials

Condition	Number of trials	Sources	Three most common dosages	Number of trials with unknown source	Number of trials with unknown dosages
Osteoathritis	169 (37.64%)	AD-MSCs – 47 (27.81%) BM-MSCs – 39 (23.07%) UC-MSCs – 27 (15.98%)	1 × 10^7–17 (10.06%) 2 × 10^7–15 (8.88%) 5 × 10^7 – 13 (7.69%)	46 (27.22%)	98 (57.99%)
Spinal cord injuries	47(10.47%)	BM-MSCs – 20 (42.55%) UC-MSCs – 8 (17.02%) AD-MSCs – 8 (17.02%)	1 × 10^6 – 7 (14.89%) 1 × 10^8–5 (10.64%) 2 × 10^7–3 (6.38%)	12 (25.53%)	26 (55.32%)
Cartilage defect	35 (7.80%)	BM-MSCs – 12 (34.29%) UC-MSCs – 7 (20.00%) AD-MSCs – 4 (11.43%)	5 × 10^7–3 (8.57%) 1 × 10^6–2 (5.71%) 2 × 10^7–1 (2.86%)	13 (37.14%)	26 (74.29%)
Fractures	35 (7.80%)	BM-MSC – 17 (48.57%) AD-MSC - 6 (17.14%) UC-MSC – 5 (14.28%);	1 × 10^7–6 (17.14%) 2 × 10^7–5 (14.29%) 4 × 10^7 – 2 (5.71%)	10 (28.57%)	19 (54.29%)
Tendinopathy	7 (1.56%)	AD-MSCs – 2 (28.57%) BM-MSCs – 1 (14.29%) Placenta MSCs – 1 (14.29%)	1 × 10^6–2 (28.57%) 2 × 10^7–2 (28.57%) 1 × 10^7–1 (14.29%)	2 (28.57%)	2 (28.57%)

Table 4 Risk of bias assessment summary

Evaluation category	Intervention and comparator	Blinding	Randomization	Outcomes	Funding	Sample
+	158 (35.2%)	328 (73.1%)	158 (35.2%)	248 (55.2%)	172 (38.3%)	247 (55.0%)
?	121 (26.9%)	67 (14.9%)	1 (0.2%)	1 (0.2%)	0 (0.0%)	188 (41.9%)
-	170 (37.9%)	54 (12.0%)	290 (64.6%)	200 (44.5%)	277 (61.7%)	14 (3.1%)

"+" indicates a low risk of bias; "?" indicates that there are some concerns; "–" indicates a high risk of bias

Table 5 The ten most common orthopaedic and traumatological conditions for which mesenchymal stem cells are utilized in systematic reviews protocols

Condition	Number of systematic reviews protocols	Completed	Published
Osteoarthritis	68 (59.65%)	17 (25%)	15 (22.06%)
Osteonecrosis	10 (8.77%)	3 (30%)	3 (30%)
Traumatic and ischemic bone lesions	6 (5.26%)	1 (16.67%)	1 (16.67%)
Articular cartilage injuries	5 (4.39%)	3 (60%)	3 (60%)
Rotator cuff injuries	4 (3.51%)	1 (25%)	1 (25%)
Degenerative disc diseases	4 (3.51%)	1 (25%)	1 (25%)
Osteochondral lesions	3 (2.63%)	1 (33.33%)	1 (33,33%)
Spinal cord injuries	2 (1.75%)	2 (100%)	2 (100%)
Tendinopathy	2 (1.75%)	1 (50%)	1 (50%)
Joint Degeneration	2 (1.75%)	0 (0%)	0 (0%)

Systematic review protocols

A search in PROSPERO identified 114 systematic review protocols. By the time of the study, 32 studies (28.10%) had been completed, with the results of 30 (26.32%) published in peer-reviewed journals.

Systematic reviews most often studied the efficacy of MSCs in the treatment of osteoarthritis (59.65%), osteonecrosis (8.77%) and traumatic and ischemic bone lesions (5.26%). At the same time, among the completed and published reviews, the highest percentage was among those studies that investigated the efficacy of MSCs in the treatment of Spinal Cord Injuries (100%), tendinopathy (50%) and articular cartilage injuries (60%) (Table 5).

Discussion

A search of major clinical trial databases revealed that the use of mesenchymal cell injections in traumatology and orthopaedics is an actively developing orthobiological method. The growth in the number of clinical trials has been explosive: while 145 trials were initiated between 2010 and 2015, this number surged to 215 between 2016 and 2021.

It should be noted that at the time of writing the review there were only 159 trials completed, i.e. only 35.4% of the total number. Moreover, many studies on this topic have not been completed within the median timeframe and their current status and results remain unknown. Furthermore, the results of only 56 (12.5%) studies were published in peer-reviewed journals. These trials most likely form the basis of the currently available systematic reviews and meta-analyses. In other words, the existing evidence base regarding the use of MSC injections for musculoskeletal pathologies relies on the results of only a small fraction of the total trials conducted. This represents a significant limitation that should be explicitly acknowledged by authors of such reviews.

Another critical issue is understanding why clinical trials often fail to reach completion, take an excessive amount of time, or remain unpublished. Common reasons include the withdrawal of funding, methodological limitations encountered during the trial, and the unwillingness or inability of the investigators to publish the results in peer-reviewed journals [20, 21]. At the same time, it is important to understand that all of the aforementioned reasons are purely hypothetical. However, the low number of publications on the results of completed clinical trials might be an indicator of risk of publication bias in this case.

The heterogeneity of MSC sources (at least 8 different types), the highly variable cell concentrations (at least 50 different dosages), and the wide age range of participants (from 18 to 75 years) revealed in the analysis cannot be overlooked. In such cases, conclusions regarding the efficacy of MSCs can only be drawn from pooled analyses of studies that utilize standardized protocols for MSC preparation and administration, involving participants with comparable age, anthropometric characteristics, and pathology. However, the available number of published clinical trials (56) does not allow this to be done in systematic reviews and meta-analyses for the vast majority of pathologies. Furthermore, there is an overrepresentation of protocols targeting some pathologies, such as osteoarthritis or Spinal Cord Injuries, whereas other prevalent conditions in traumatology, including tendinopathies and ligament injuries, remain insufficiently represented.

Another important issue is the complete absence of participants meeting the definition of athletes in the trials despite this group being the most demanding in terms of treatment outcomes [22–24]. It is also the group that may often use treatments for injuries limited evidence of effectiveness [25–27]. At the same time, according to the social media and news reports, it is quite common for elite athletes to be offered this procedure as an option to treat their injuries [16].

Regarding athletes, it is important to highlight that the procedure of obtaining MSCs by the most commonly used methods (adipose tissue sampling from the anterior abdominal wall and bone marrow sampling from bone puncture) can be quite traumatic [28, 29]. These procedures frequently necessitate a reduction or complete cessation of training loads and may be accompanied by complications including tissue fibrosis, allergic reactions, localized infections, and pain at the injection site [30–32]. For athletes (e.g., professional football players), the most appropriate and valid way to obtain MSCs is bone puncture, as their adipose tissue content is often minimal, ranging between 9.41 and 10.97% [33].

This study has several limitations. First, not all researchers may have fully updated the clinical trial registries regarding study completion status or subsequent publication in peer-reviewed journals. Second, the results of some trials may still be undergoing peer review, given the often lengthy nature of the publication process. Third, detailed information on the methodologies used for mesenchymal stem cell (MSC) processing and stromal vascular fraction (SVF) preparation was unavailable, as such data were not consistently reported in the majority of trial protocols. Finally, no assessment of literature quality or risk of bias was performed, which limits the ability to critically appraise the methodological rigor of the included RCTs protocols. Future studies should focus on the effectiveness of this methodology in athletes, as this population has the highest physical activity demands.

Conclusions

MSC injections represent a growing area of research in traumatology and orthopaedics. However, the results of only a small proportion of clinical trials and systematic reviews are published in peer-reviewed journals, which most likely does not allow practitioners to form a full judgement on the efficacy and safety of this treatment. Thus, any data on the efficacy (or lack thereof) currently available can be assessed as preliminary and requiring additional research.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12891-025-09123-8.

Supplementary Material 1

Supplementary Material 2

Author contributions

Data collection was performed by G.M, I.D., M.K. and M.I.; data analysis and interpretation were performed by E.B., G.M., M.K., E.S. and I.D.; research concept and study design were developed by E.B., G.M. and E.G. Literature review performed by E.B., G.M. and A.Z. Statistical analysis was performed by E.K. and E.G. The first draft of the manuscript was written by E.B. and G.M. Reviewing and editing were performed by I.D., M.K., A.Z., M.I., E.S. and E.K. All authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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Data availability

the datasets used and/or analysed during the current study are available as a supplementary file.

Declarations

Ethics approval and consent to participate

not applicable. Local ethics committee approval was not required since publicly available data were utilized. The study was conducted according to the Helsinki declaration. The data were obtained from open access sources, therefore no informed consent for study participation was necessary.

Consent for publication
not applicable.

Competing Interests
The authors declare no competing interests.

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