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OPEN PEER REVIEW

Efficacy of Ultrasound-Guided Platelet-Rich Plasma (PRP) Injection in Patients with Sacroiliac Joint Pain: A Single-Arm, Before and After, Open-Label Clinical Trial

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About this report

This open peer review (OPR) report shows the public comments made on this article during peer review, by the reviewers, the associate editor and the editor-in-chief, for every revision round, together with the authors' replies. Comments appear only with the consent of the people who wrote them. Reviewers who chose to sign their report are named; the others are shown as "Referee". Comments are edited for language only, and confidential remarks to the editors are not included.

More about open peer review: brieflands.com/knowledgebase/opr

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1 Original submission

2 comments · 12 Dec 2024 – 12 Dec 2024

Associate Editor

MINOR REVISION 12 Dec 2024

Dear EIC,
Thanks to the authors and appreciation to the researchers. The authors aimed to assess the impact of platelet-rich plasma (PRP) injections in patients with chronic SIJ pain unresponsive to conservative treatments. The manuscript presents valuable research. But some revisions are needed. The authors should revise it based on the reviewers' comments.

Also, a minor change should be made in the abstract:
The study design should be mentioned in the first line of the method section of the ABSTRACT.

Editor-in-Chief

MINOR REVISION 12 Dec 2024

Dear Author,
Thank you for submitting the article. It needs some revision. Please revise it based on the reviewers' and AE's comments.

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Revision 1

AUTHORS' RESPONSE TO REVIEWERS

Authors' reply to reviewers

The next pages contain the authors' point-by-point reply to the comments of this revision round, as submitted with the revised manuscript. It is published as the authors wrote it.

Reviewers' Comments:

Reviewer 1:
The abstract provides a clear summary, but additional details on the randomization process and blinding (if applicable) would enhance the understanding of the study's design.

Answer: Thank you for your valuable comment. As we mentioned in the methods section, this study is a single-arm, open-label clinical trial and randomization or blinding are not applicable in this design, while we don't have a control group. We have edited and clarified our study's design in the Abstract section to avoid any confusion. Thank you once again for valuable feedback.

Reviewer 2:
Dear editor
Dear author
Hi

The article was reviewed, despite the fact that there are similar topics in Google searches, but given the novelty of this method and its lack of registration in the texts, Conducting similar studies would help strengthen the results.
The title selection and abstract sections are well written.
It is better to have a keyword pattern based on MESH.
Writing principles have been followed in the introduction and method.
Figure and tables related to the text are included.
References related to each paragraph are included at the end of the article, but it is recommended that each reference be linked with EndNote software.
Kind Regards

Answer: Thank you very much for your valuable comment. We revised our keywords, and made sure of their accordance to the MESH terms. We used the Mendeley software, which is a free equivalent for Endnote software. But we double-checked our references and made sure that the references are in accordance with journal guidelines. Thanks again for your valuable comments.

Reviewer 3:

THANKS FOR THE VERY WELL-DESIGNED STUDY AND STRUCTURED AND HIGH QUALITY MANUSCRIPT WRITING.
I ACTUALLY ENJOYED REVIEWING THE ARTICLE.

Answer: Thank you very much for your kind words and positive feedback regarding our study and manuscript. We are thrilled to hear that you enjoyed reviewing our article.

Associate Editor's Comments:

Associate Editor 1:
Dear EIC,
Thanks to the authors and appreciation to the researchers. Authors aimed to assess the impact of platelet-rich plasma (PRP) injections in patients with chronic SIJ pain unresponsive to conservative treatments. The manuscript is a valuable research. But some revisions are needed. Authors should revise it based on reviewers comments.

Also minor change should be done in abstract:
Study design should be mentioned in first line of method section of ABSTRACT

Answer: Dear Editor,

Thank you for your thoughtful feedback and for the opportunity to revise our manuscript.

We are committed to addressing the reviewers' comments thoroughly. We revised the abstract of our manuscript accordingly as well. Thanks again for your valuable comments.

EIC Decision:

Dear Author,
Thank you for submitting the article. It needs some revision. Please revise it based on Reviewers and AE comments.

Reviewer Assistant Comments:

These comments were generated by AI based on your manuscript. Please review them and consider incorporating the suggestions to enhance your article.

The abstract provided describes a clinical trial. Based on the study design mentioned in the abstract, "A Single-Arm, before and after, open-label Clinical trial," the appropriate checklist to use for the peer review is the CONSORT checklist for Randomized Trial Studies. I will now proceed to perform the peer review using the CONSORT checklist.

Peer Review Using CONSORT Checklist

1. **Title and Abstract:**
    - **Question:** Does the title and abstract provide a clear and accurate summary of the trial?
    - **Peer Review:** The title clearly indicates the study's focus on the efficacy of ultrasound-guided PRP injection for SIJ pain. The abstract provides a concise summary of the background, aim, methods, results, and conclusions.
2. **Introduction:**
    - **Question:** Is the scientific background and rationale for the trial clearly explained?
    - **Peer Review:** The background explains the burden of SIJ pain and the potential benefits of PRP, providing a rationale for the study.
3. **Participants:**
    - **Question:** Are the eligibility criteria for participants clearly defined?
    - **Peer Review:** The eligibility criteria are specified as patients aged 30 to 80 years with chronic SIJ pain unresponsive to conservative treatments.
4. **Interventions:**
    - **Question:** Are the interventions for each group clearly described?

- **Peer Review:** The intervention is clearly described as PRP prepared from autologous blood and injected into the SIJ under ultrasound guidance.

5. **Outcomes:**
    - **Question:** Are the primary and secondary outcome measures clearly defined?
    - **Peer Review:** The primary outcomes are pain intensity and functional disability, measured using NRS and MODI, respectively.
6. **Sample Size:**
    - **Question:** Is the sample size determined and justified?
    - **Peer Review:** The abstract mentions 16 patients were included, but there is no justification or calculation for the sample size.
7. **Statistical Methods:**
    - **Question:** Are the statistical methods used to compare groups for primary outcomes clearly described?
    - **Peer Review:** Statistical analysis was conducted using repeated measures ANOVA to evaluate changes over time.
8. **Results:**
    - **Question:** Are the results for each group, including the estimated effect size and its precision, clearly reported?
    - **Peer Review:** Results are reported with mean values and standard deviations for pain intensity and MODI scores at different time points, indicating statistically significant changes.
9. **Adverse Events:**
    - **Question:** Are all important adverse events or side effects reported?
    - **Peer Review:** No significant adverse events were reported.
10. **Discussion:**
    - **Question:** Does the discussion address the trial's limitations, potential biases, and generalizability?

- **Peer Review:** The conclusion suggests further studies with larger samples and prolonged follow-ups, indicating an acknowledgment of limitations.

Categorization of Comments

Major Comments:

- The sample size is small, and there is no justification or calculation provided for the sample size, which is crucial for the reliability of the study's conclusions.

  Answer: Thank you for your valuable comment. We understand your concern regarding the small sample size. The recent study is a single arm explanatory clinical trial. The main objective is safety and then crude efficacy for study intervention. In explanatory studies the sample between 10 to 15 could show the efficacy from 20 to 30 percent. However, the small sample size is the limitation of our study which we have mentioned in the limitations section. We have added an explanation for the rationale behind the sample size to the discussion.

Minor Comments:

- The abstract provides a clear summary, but additional details on the randomization process and blinding (if applicable) would enhance the understanding of the study's design.

  Thank you for your valuable comment. As we mentioned in the methods section, this study is a single-arm, open-label clinical trial and randomization or blinding are not applicable in this design, while we don’t have a control group. We have edited and clarified our study’s design in the Abstract section to avoid any confusion. Thank you once again for valuable feedback.

- While the results are statistically significant, a discussion on the clinical significance of the findings would be beneficial.

  Answer: We discussed the clinical significance of our results in the discussion section, we also made modification to the conclusion section of our abstract, in order to enhance the clarity of our abstract. Thanks for your valuable comment.

2 Revision 1

2 comments · 18 Dec 2024 – 18 Dec 2024

Associate Editor

ACCEPT 18 Dec 2024

Dear EIC.
Previous errors have been corrected, and there are no further recommendations.

Editor-in-Chief

ACCEPT 18 Dec 2024

Dear Authors.
Your revisions have significantly improved the article, and it is now deemed acceptable for publication.
Congratulations on your hard work and dedication to enhancing the quality of your work.