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OPEN PEER REVIEW

The Effect of Intrauterine Administration of Growth Hormone on IVF Success Rate in Recurrent Implantation Failure Women: A Randomized 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.

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1 Original submission

1 comment · 9 Sep 2024

Referee 1 Reviewer

MAJOR REVISION 9 Sep 2024

hello. With thanks,
I have a question about the groups in which endometrial thickness did not increase after GH infusion:
Why did you not exclude them?

2

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.

Dear Reviewer 1:

Thanks for your valuable comments, please here find the responses.

-i have question about groups, that after infusion of GH and non icreasing endometrial thichness: why you didnt exclude?

Because the patient did not agree to use surrogated uterus and wanted to transfer the embryo into her own uterus. In addition, in some cases with an endometrial thickness less than optimal, the embryo was transferred, and favorable results were reported.

Dear Reviewer 2:

Thanks for your valuable comments, please here find the responses.

-The manuscript has several structural and grammmatical errors. It is recommended to rewrite to improve English writing.

It was edited.

-In Abstract, verbs should be written as past time ot future. And structure of it, should be revised.

It was edited.

-In several parts of the text, the authors, have been used, perfusion, injection, infusion, application for administration. Please write intravaginal administration.

It is not intravaginal administration, it is intrauterine administration. All words (perfusion, injection, infusion, application) replaced with administration.

-What is your mean of "suppository tablet"?

If pregnancy happened, 400 mg vaginal progesterone was continued daily until the 8th weeks of pregnancy.

-It is recommended to explain about calculation of sample size, blindness, randomization and safety.

was added.

-Please mention to limitation of the study.

was added.

-Revise the exclusion and inclusion criteria.

Was revised.

-In table 1, Asherman and Endometriosis are listed in intervention group, whereas they are listed as exclusion!!!!

It was edited.

1. **Title and Abstract**
- **Title**: The title identifies the study as a randomized trial.
- **Abstract**: The abstract should provide a structured summary of trial design, methods, results, and conclusions, which appears to be missing in the provided text.

2. **Introduction**
- **Background and Objectives**: The background explains the rationale for the study, and the objectives are clearly stated.

3. **Methods**
- **Trial Design**: The study design is described as a randomized double-blind clinical trial.
- **Participants**: Eligibility criteria are mentioned (infertile women diagnosed with RIF), but details on the selection process and settings could be more explicit.
- **Interventions**: The intervention (intrauterine infusion of GH) and control (presumably a placebo) are described, but details on how and when they were administered could be clearer.
- **Outcomes**: The primary outcomes (endometrial thickness, quality, and pregnancy rate) are defined, but the timing of these assessments is not specified.
- **Sample Size**: The sample size (60 women) is mentioned, but the method for determining this size is not provided.
- **Randomization**: The method of randomization is not detailed, including the sequence generation and allocation concealment.
- **Blinding**: It is stated that the trial is double-blind, but specifics on who was blinded and how are not provided.
- **Statistical Methods**: The statistical methods used to compare groups for primary and secondary outcomes are not detailed.

4. **Results**
- **Participant Flow**: There is no flow diagram provided showing the numbers of participants at each stage of the trial.
- **Baseline Data**: There is no table or description of baseline demographic and clinical characteristics for each group.
- **Numbers Analyzed**: The number of participants analyzed for each outcome is not specified.
- **Outcomes and Estimation**: Results for each primary and secondary outcome are mentioned, but effect sizes and confidence intervals are not provided.

5. **Discussion**
- **Limitations**: The limitations of the trial are not discussed.
- **Generalisability**: There is no mention of the generalizability of the findings.
- **Interpretation**: The interpretation of results is somewhat vague and lacks depth.

6. **Other Information**
- **Registration**: There is no mention of trial registration.
- **Funding**: There is no information provided regarding funding sources.

Summary of Findings
The study provides a foundational understanding of the effects of GH on IVF success rates in RIF women. However, it lacks several critical elements as per the CONSORT guidelines, particularly in the methods and results sections. Enhancements in clarity regarding randomization, blinding, statistical methods, and comprehensive reporting of results would

strengthen the manuscript significantly.

Recommendations
- Include a structured abstract summarizing the trial.
- Provide detailed methods for randomization and blinding.
- Include a flow diagram for participant flow.
- Report baseline characteristics and outcomes with effect sizes and confidence intervals.
- Discuss limitations and generalizability of the findings.
- Mention trial registration and funding sources.

This evaluation highlights the importance of adhering to reporting guidelines to ensure the transparency and reproducibility of clinical trials.

All revisions that ai reviewer was requested were added in the manuscript.

2 Revision 1

0 comments

No public comments in this round.