INPLASY PROTOCOL

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None declared.

Efficacy of intracytoplasmic sperm injection in women with non-male factor infertility: A systematic review and meta-analysis

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Review question / Objective: **This meta-analysis aims to evaluate whether intracytoplasmic sperm injection (ICSI) improved reproductive outcomes for non-male factor infertility versus in vitro fertilization (IVF).**
Condition being studied: **The use of ICSI has increased dramatically in recent years and is being applied for indications other than male factor infertility. However, despite its increased use, there is no clear evidence of the benefit of using ICSI over conventional IVF for non-male factor infertility.**
Eligibility criteria: **Studies will be excluded if one of the following conditions is met: (1) unqualified male perm count and motility; (2) rescued ICSI; (3) non-RCTs of study design; (4) a significant amount of research data is missing or not available.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 03 April 2023 and was last updated on 03 April 2023 (registration number INPLASY202340003).

INTRODUCTION

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METHODS

Search strategy: **A comprehensive search of the following databases from inception**

until March 2023 was conducted: MEDLINE(via Pubmed), Embase, and Cochrane Central Register of Controlled Trials (CENTRAL). Keywords included "non–male factor", "female factor", "normozoospermia", "Injection, Intracytoplasmic Sperm", "Injections, Intracytoplasmic Sperm", "Intracytoplasmic Sperm Injection", "Sperm Injection, Intracytoplasmic", "Intracytoplasmic Sperm Injections", "ICSI" and "Injections, Sperm, Intracytoplasmic". Only English publications were included.

Participant or population: Participants were diagnosed with infertility with non-male factors regardless of etiology, and the male's sperm count and motility were assessed according to the World Health Organization (WHO) criteria.

Intervention: ICSI.

Comparator: Conventional IVF.

Study designs to be included: Randomised controlled trials.

Eligibility criteria: Studies will be excluded if one of the following conditions is met: (1) unqualified male perm count and motility; (2) rescued ICSI; (3) non-RCTs of study design; (4) a significant amount of research data is missing or not available.

Information sources: In addition to the electronic databases, as described in the Search strategy, reference lists of included studies and relevant reviews, conference proceedings, and websites of the clinical trial registry were hand-searched to identify additional studies.

Main outcome(s): 1. Live birth rate; 2. Fertilization rate; 3. Total fertilization failure.

Additional outcome(s): 1. Clinical pregnancy rate; 2. Miscarriage rate; 3. Implantation rate; 4. Good-quality embryo rate.

Quality assessment / Risk of bias analysis: Two authors independently assess the risk of bias of the included studies according to the Cochrane Handbook for Systematic Reviews of Interventions version, considering the following characteristics: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective data reporting, and other sources of bias. Disagreements will be resolved by discussed with a third reviewer.

Strategy of data synthesis: We calculated risk ratio (RR) with 95% confidence intervals (CIs) for all dichotomous outcomes. Given the clinical heterogeneity between studies due to different study protocols and participant characteristics, we used a random-effects model to produce overall estimates in RevMan software. We measured heterogeneity using the I2 statistic, considering an I2 > 50% to be substantial heterogeneity. We aim to assess the publication bias using a funnel plot if at least ten studies are included in the meta-analysis, according to the Cochrane Handbook recommendations. The GRADE approach will be performed to evaluate each outcome's certainty of evidence.

Subgroup analysis: Subgroup analyses and meta-regression will be conducted to find potential factors influencing the outcomes. The main factors for subgroup analyses are unit of randomization, female age, study year, and protocol of controlled ovarian hyperstimulation.

Sensitivity analysis: Studies with only low risk of bias (both selection and attrition bias were rated as low risk) will be calculated for sensitivity analysis.

Language restriction: English.

Country(ies) involved: China.

Keywords: Intracytoplasmic sperm injection, non-male factor, infertility, ICSI.

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