

# INPLASY PROTOCOL

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**Conflicts of interest:**  
None declared.

## Effect of Traditional Chinese Medicine on the Treatment of Male Infertility Caused by Sperm DNA Fragmentation: A Systematic Review and Meta-Analysis

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**Review question / Objective:** To evaluate the efficacy and safety of Traditional Chinese Medicine (TCM) on the treatment of male infertility due to sperm DNA fragmentation (SDF).

**Condition being studied:** Andrology.

**Eligibility criteria:** The inclusion criteria were as follows: (1) The studies included must be RCTs on the treatment of male infertility associated with SDF used TCM; (2) the control group was placebo or guideline-recommended oral medication; (3) male patients (aged 18-60 years) were diagnosed with MI according to the World Health Organization guidelines.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 01 April 2022 and was last updated on 01 April 2022 (registration number INPLASY202240007).

### INTRODUCTION

**Review question / Objective:** To evaluate the efficacy and safety of Traditional Chinese Medicine (TCM) on the treatment of male infertility due to sperm DNA fragmentation (SDF).

**Condition being studied:** Andrology.

### METHODS

**Participant or population:** Male Infertility Caused by Sperm DNA Fragmentation.

**Intervention:** Traditional Chinese Medicine.

**Comparator:** Placebo or guideline-recommended oral medication.

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**Study designs to be included:** Random control trials.

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**Information sources:** Two reviewers (QZ and FY) researched independently the electronic databases including PubMed, EMBASE, Cochrane Library, Web of Science, the China National Knowledge Infrastructure (CNKI), the China Science and Technology Journal database (VIP), and the Wanfang database from their establishment to March 1st 2022. Grey literature had also been searched in retrieve dissertations, ongoing experiments, grey literature, conference and unpublished documents.

**Main outcome(s):** The main outcomes of the review included SDF index, pregnant rate, semen parameters (concentration, motility, morphology) and safety outcomes.

**Quality assessment / Risk of bias analysis:** Risk of bias (ROB) assessment tool would be used to evaluate the quality of each literature. There were six biases including sequence generation, allocation concealment, blinding of outcome assessment, incomplete outcome data, selective reporting and others bias according to the Cochrane Risk of Bias Assessment tool.

**Strategy of data synthesis:** Data synthesis were performed by the software RevMan 5.3. Mean difference (MD) and 95% confidence interval (CI) would be recorded for continuous variable outcome. For dichotomous outcomes, we recorded the relative risk (RR) and 95% CI. Statistical heterogeneity was represented by a standard  $\chi^2$  test with a significance level of  $p < 0.1$ , and an  $I^2$  test was used for quantifying inconsistency among the

included studies. When  $I^2 < 50\%$  and  $P \geq 0.1$ , a fixed-effect model will be used and a random-effects model will be use when  $I^2 \geq 50\%$  or  $P < 0.1$ .

**Subgroup analysis:** If the heterogeneity was high, the subgroup analysis were performed to analyze the cause of heterogeneity, such as different methods to measure SDF.

**Sensitivity analysis:** And the sensitivity analysis was conducted to combine the effect sizes after excluding each included study one by one, so as to evaluate the robustness and reliability of the combined results of the meta-analysis.

**Country(ies) involved:** China.

**Keywords:** Sperm DNA Fragmentation; Male Infertility; Traditional Chinese Medicine; Systematic Review.

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