INPLASY

Traditional Chinese medicine for asthenozoospermia and oligoasthenozoospermia: a scoping review of registered intervention trials in major trial registries

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ADMINISTRATIVE INFORMATION

Support - Jointly Established Research P.

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Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 8 April 2026 and was last updated on 8 April 2026.

INTRODUCTION

Review question / Objective Review question: This scoping review aims to answer the following question: What is the current state of registered clinical trials on Traditional Chinese Medicine (TCM) for asthenozoospermia and oligoasthenozoospermia in terms of trial registration characteristics (temporal trends, geographic distribution, registry platforms), trial design features (sample size, blinding, randomization, intervention types, control types, outcome measures), and methodological quality indicators?

Objectives:
The specific objectives of this review are:
To identify all registered interventional trials on TCM for asthenozoospermia and oligoasthenozoospermia from major global registries (Chinese Clinical Trial Registry (ChiCTR), the International Traditional Medicine Clinical Trial Registry (ITMCTR), European Union Drug Regulating Authorities Clinical Trials Database (EudraCT), University Hospital Medical Information Network (UMIN) and ClinicalTrials.gov).

To describe the temporal trends and geographic distribution of these registered trials.

To map and summarize key trial characteristics, including sample size, randomization, blinding, intervention categories (herbal medicine, acupuncture, combination therapy, etc.), control types, and primary/secondary outcome measures.

To evaluate the completeness and clarity of registry entries against standard reporting requirements.

To identify methodological gaps and provide actionable recommendations for improving future trial design and registration practices in TCM male infertility research.

Background Male infertility is often associated with reduced sperm motility. This study focuses on two related but distinct conditions:

asthenozoospermia (defined as isolated low sperm motility with normal sperm count) and oligoasthenozoospermia (defined as low sperm motility combined with low sperm count). While assisted reproductive technology (ART) has advanced, it remains costly, invasive, and not suitable for all. Thus, safe, effective, and accessible alternatives are of significant clinical and social value.

Traditional Chinese medicine (TCM) has a long history and unique theoretical system (e.g., "kidney stores essence," "tonifying the kidney") for treating male infertility, especially improving sperm quality. Numerous studies suggest TCM therapies (herbal formulas, acupuncture) may enhance sperm density, motility, morphology, and DNA integrity. However, clinical research quality is inconsistent, and higher-level, systematic evidence is needed to support TCM's efficacy and safety.

Rationale Clinical trial registration has been recognized as an effective mechanism to improve transparency, reduce publication bias, and avoid duplication. More importantly for this study, registries offer a unique window to map the design landscape of ongoing and completed trials—including their interventions, comparators, and outcome measures—before results are formally published. However, no study has comprehensively reviewed registered TCM trials for asthenozoospermia and oligoasthenozoospermia from a global perspective. Therefore, it remains unknown whether existing or ongoing trials have addressed the methodological shortcomings identified in the literature (e.g., lack of blinding, small sample sizes, heterogeneous outcomes), or whether new trial designs are needed to generate internationally acceptable evidence.

This study reviews registered TCM trials for asthenozoospermia and oligoasthenozoospermia on major global platforms. We depict the overall landscape (temporal trends, geographical distribution, platform characteristics) and conduct an in-depth analysis of trial design, interventions (herbal formulas, acupuncture, combination therapy, etc.), control types, outcome measures. We then identify key gaps and provide actionable recommendations to foster high-quality, internationally recognized trials, advance evidence-based TCM, and ultimately offer a robust treatment basis for male infertility patients worldwide.

METHODS

Strategy of data synthesis As this is a scoping review designed to map the existing literature rather than to synthesize effect estimates, no meta-analysis will be performed. The synthesis strategy will be purely descriptive and will follow the PRISMA-ScR reporting guidelines.

Data presentation: Extracted data will be organized into summary tables structured around the following domains: (1) trial registration characteristics (registry platform, registration year, country of origin, recruitment status); (2) trial design features (sample size, randomization method, blinding procedures, intervention types, control types); and (3) outcome measures .

Visualization: Descriptive statistics (frequencies and percentages) will be calculated for categorical variables. The following visualizations will be generated: (1) a bar chart showing annual trends of registered trials over time; (2) a world map or regional bar chart displaying geographic distribution of trials.

Narrative synthesis: Key findings will be summarized narratively, with particular attention to identifying methodological patterns (e.g., proportion of trials reporting blinding or sample size calculation), common deficiencies (e.g.,absence of pregnancy outcomes), and notable gaps (e.g., underrepresentation of certain geographic regions or trial designs). Where appropriate, findings will be discussed in relation to existing methodological recommendations for TCM clinical trials in male infertility.

Eligibility criteria Registered trials were eligible if they included male participants diagnosed with asthenozoospermia or oligoasthenozoospermia. Regarding the diagnostic criteria for these conditions, we did not impose a standardized definition a priori, as the primary objective of this scoping review was to map the existing registered trials and their characteristics. Instead, we accepted the diagnostic criteria as defined by each individual trial protocol, recognizing that diagnostic standards may vary across studies, regions, and time periods. The intervention/treatment was TCM, which included Chinese herbal medicine (decoction, granules, pills, tablets, powder, capsules, extracts, etc.), acupuncture (electroacupuncture), moxibustion, etc.

Source of evidence screening and selection

Data sources and search:

A systematic search was conducted in the following five clinical trial registries: Chinese Clinical Trial Registry (ChiCTR), International Traditional Medicine Clinical Trial Registry (ITMCTR), European Union Drug Regulating Authorities Clinical Trials Database (EudraCT), University Hospital Medical Information Network

Clinical Trials Registry (UMIN-CTR), and ClinicalTrials.gov. The search was performed for records available up to December 31, 2025.
Search results:
As of December 31, 2025, a total of 161 relevant records were retrieved from the five registries.

Screening and selection process:

The selection of eligible trials followed a two-stage process:

Duplicate removal and initial screening: All retrieved records were examined for duplicates. Records that were clearly irrelevant to the research question were removed at this stage.

Eligibility assessment: The remaining records were assessed against pre-defined inclusion and exclusion criteria to determine final eligibility.

Following this process, 35 trials meeting the inclusion and exclusion criteria were finally included.

Data extraction:

Data extraction was performed independently by two researchers (Z.X. Chen and Z.F. Jin) using a pre-determined standardized form. The extracted variables included: registration number, location, registration date, design type, blinding, age range, sample size, intervention, primary outcome measures, number of centers, and trial life cycle status.

Handling of missing data:

For missing or incompletely reported data, the detailed description within each registry entry was checked to supplement information where possible. If data remained unavailable after this check, "not reported (N/A)" was recorded.

Handling of disagreements:

Any disagreement between the two researchers during data extraction was resolved through discussion. If consensus could not be reached, a third reviewer (C.Y.Z. Wen) was consulted to make the final decision.

Reporting:

The complete data extraction form.

Data management Data management

Data collection tools: A standardized data extraction form will be created using Microsoft Excel. The form will include the following fields: registration number, location, registration date, design type, blinding, age range, sample size, intervention, primary outcome measures, number of centers, and trial life cycle status.

Data storage and security: All extracted data will be stored on a password-protected institutional computer. A backup copy will be maintained on a secure institutional cloud drive (or external hard drive), updated weekly. Only the research team members (Z.X. Chen, Z.F. Jin, and C.Y.Z. Wen) will have access to the raw data.

Data processing: Data will be cleaned and coded prior to analysis. Categorical variables will be coded as numerical values (e.g., 1 = yes, 0 = no) for statistical analysis. Descriptive statistics (frequencies, percentages, means, and standard deviations) will be calculated using SPSS (or R, Microsoft Excel).

Missing data handling: For missing or incomplete registry entries, the detailed description within each registry will be checked for supplementary information. If data remain unavailable, "not reported (N/A)" will be recorded. No imputation of missing data will be performed.

Data sharing: The complete data extraction form will be made available as a supplementary file with the published review. Raw data will be available from the corresponding author upon reasonable request.

Long-term preservation: The dataset will be preserved for at least 5 years after publication on the corresponding author's institutional storage.

Reporting results / Analysis of the evidence
Overall approach: As this is a scoping review designed to map the existing literature rather than to synthesize effect estimates, no meta-analysis will be performed. The analysis will be purely descriptive, following the PRISMA-ScR reporting guidelines.

Descriptive statistics: Descriptive statistics will be calculated for all extracted variables. Categorical and continuous variables (e.g., registry platform, design type, blinding, intervention type, control type, sample size, age range, number of centers) will be summarized using frequencies and percentages.
Visualization: The following visualizations will be generated to present the findings:

Bar chart: Annual trends of registered trials over time (by registration year)

Bar chart or world map: Geographic distribution of trials by country/region
PRISMA flow diagram: Study selection process

Structured tables: Extracted data will be organized into summary tables covering:

Table 1: General characteristics of included trials (registration number, platform, country, registration date, sample size, trial status)

Table 2: Methodological design features (randomization, blinding, control type, number of centers)

Table 3: Intervention characteristics (type, duration, comparator)

Missing data handling: Missing or incompletely reported data will be recorded as "not reported (N/A)" in all tables
Narrative synthesis: Key findings will be summarized narratively, with particular attention to;

Software: Descriptive statistics and visualizations will be performed using Microsoft Excel .

Reporting standard: The results will be reported in accordance with the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) checklist.

Overall landscape and temporal/spatial patterns of registered TCM trials for asthenozoospermia and oligoasthenozoospermia.

Presentation of the results Presentation of the results
The results will be presented in accordance with the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) guidelines. The presentation will include the following components:
PRISMA flow diagram: The study selection process will be presented as a PRISMA-ScR flow diagram (Figure 1), showing the number of records identified, screened, assessed for eligibility, and finally included, along with reasons for exclusion.
Summary tables: Extracted data will be organized into structured summary tables:

Supplementary File: General characteristics of included trials (registration number, registry platform, country of origin, registration date, sample size, trial life cycle status, age range)

Table 1: Methodological design features (study design type, randomization method, blinding procedures, control types, number of centers), Intervention characteristics, Outcome measures

Visualizations: The following figures will be generated to visually summarize the findings:

Figure 2: Bar chart showing annual trends of registered trials over time (by registration year)

Figure 3: Bar chart or world map displaying geographic distribution of trials by country/region
Narrative summary: A structured narrative synthesis will accompany the tables and figures, organized into the following sections:

Overall landscape of registered TCM trials for asthenozoospermia and oligoasthenozoospermia

Temporal trends and geographic distribution

Trial design characteristics (sample size, randomization, blinding, controls)

Intervention patterns (herbal medicine, acupuncture, combination therapy)

Outcome measures and reporting completeness

Methodological gaps and common deficiencies

Supplementary materials: The complete data extraction form will be provided as a supplementary file (Supplementary File 2). Raw data will be available from the corresponding author upon reasonable request.
Order of presentation: Results will be presented in the following order: (1) study selection process (flow diagram); (2) general characteristics of included trials; (3) temporal and geographic patterns; (4) trial design features; (5) intervention and control characteristics; (6) outcome measures; and (7) methodological gaps and deficiencies.

Language restriction Only trials registered in English or Chinese will be included, as the research team is proficient in both languages.

Country(ies) involved China.

Other relevant information No

Keywords traditional Chinese medicine; asthenozoospermia; oligoasthenozoospermia; registered clinical trials.

Contributions of each author

Author 1 - Caiyuzhu Wen - CaiYuZhu Wen conceived the manuscript idea.
Email: wcyzhu@126.com
Author 2 - ZhiXu Chen - filtered the articles and performed data extraction.
Author 3 - ZhenFei Jin - filtered the articles and performed data extraction.
Author 4 - LiNa Zhao - analyzed the data and completed the graphs.
Author 5 - YaFei Liu - analyzed the data and completed the graphs.
Author 6 - Jianshe Chen - provided a critical version of the manuscript.