

INPLASY PROTOCOL

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Corresponding author:
Qisheng Wang

wqstnyy@163.com

Author Affiliation:
The People's Hospital of
Xinchang Zhejiang Province
P.R. China.

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None declared.

A meta-analysis of azithromycin treatment for *Ureaplasma urealyticum* in female reproductive tract

Wang, QS¹; Zhang, L²; Liang, ZY³.

Review question / Objective: The aim of this study was to evaluate the efficacy of azithromycin in the treatment of *Ureaplasma urealyticum*. Is it safe to compare other antibiotics to azithromycin when treating *Ureaplasma urealyticum* infection?

Condition being studied: *Ureaplasma* species are the most prevalent genital *Mycoplasma* isolated from the urogenital tract of both men and women. *Ureaplasma* has 14 known serotypes and is divided into two biovars- *Ureaplasma parvum* and *Ureaplasma urealyticum*. The organisms are tested against azithromycin, josamycin, ofloxacin and doxycycline. Resistance to macrolides, tetracyclines and fluoroquinolones have been reported. Prompt diagnosis and initiation of appropriate antibiotic therapy is essential to prevent long term complications of *Ureaplasma* infections. At present, guidelines and expert consensus on *Ureaplasma urealyticum* have been released in mainland China and internationally, indicating that there is no unified treatment plan for azithromycin treatment of *Ureaplasma urealyticum*.

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 INPLASY202240001).

INTRODUCTION

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METHODS

Participant or population: Participating female patients must be diagnosed according to the diagnostic criteria. No Limit study subjects by age, race, and severity of illness.

Intervention: Azithromycin.

Comparator: Comparing the safety and efficacy of azithromycin with quinolone antibacterial drugs and other antibacterial drugs.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: The study included acute and chronic female reproductive tract infections confirmed by microbiological testing.

Information sources: From the earliest to March 2022, published RCTs will be retrieved by searching PubMed, Embase, Cochrane Library, Web of Science, China National Knowledge Infrastructure (CNKI), Wan Fang database. We will use the following search terms: randomized controlled trial, *Ureaplasma urealyticum*, Azithromycin.

Main outcome(s): *Ureaplasma urealyticum* clinical trial is negative, the treatment is safe and effective.

Quality assessment / Risk of bias analysis: We will use the Cochrane Collaboration's tool which is recommended by the Cochrane Reviewer's Handbook to assess risk of bias for quality assessment of the included studies. The studies will be graded based on: (i) random sequence generation; (ii) allocation concealment; (iii) blinding; (iv) incomplete outcome data; (v) selective outcome reporting; (vi) other sources of bias.

Strategy of data synthesis: The data of the study included may be divided into two cases, depending on whether the data are suitable for meta-analysis. If the meta-analysis will not be performed because of heterogeneity, interventions, comparisons, outcomes etc., we will make forms for a qualitative description. If the data is suitable for meta-analysis, we will perform the meta-analysis using software RevMan 5.3 (Review Manager). For dichotomous data, we will present the results as risk ratios (RR) with 95% confidence intervals (CIs). For continuous data, the mean difference (MD) will be presented. If outcome variables are measured on different scales, standard mean differences (SMD) analysis with 95% CIs will be performed. For the data will be done with the meta-analysis, the heterogeneity will be tested by a standard I^2 test. If there is no statistic heterogeneity among the results, the fixed effects model is employed for meta-analysis. If there is a statistic heterogeneity, the source of the heterogeneity should be further analyzed. If there is obvious clinical heterogeneity, the subgroup or sensitivity analysis, or only descriptive analysis can be performed.

Subgroup analysis: We will carry out Type-Based Subgroup Analysis *Ureaplasma urealyticum* infection of the reproductive tract.

Sensitivity analysis: We will conduct a sensitivity analysis to verify the robustness of the research conclusions, assess the methodological quality, the study design, the effect of sample size and missing data, and the effect of the analysis method

on the results of this review . the meta-analysis will be repeated ,and lower-quality studies will be excluded. These results will then be compared and discussed.

Country(ies) involved: China.

Keywords: *Ureaplasma urealyticum*; azithromycin; reproductive tract infection.

Contributions of each author:

Author 1 - Qisheng Wang - The author drafted the manuscript.

Email: wqstnyy@163.com

Author 2 - Lin Zhang - The author provided statistical expertise.

Email: zhanglinfudan@zju.edu.cn

Author 3 - Zuyu Liang - The author contributed to the development of the selection criteria, and the risk of bias assessment strategy.

Email: surp2007@126.com