INPLASY PROTOCOL

To cite: Yuan et al. The effectiveness and safety of Sun's tip-flexible ureterorenoscope for the management of kidney stones:A protocol for systematic review and metaanalysis of randomized controlled trials. Inplasy protocol 2020110099. doi: 10.37766/inplasy2020.11.0099

Received: 22 November 2020

Published: 23 November 2020

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Support: Science and Technology Bureau.

Review Stage at time of this submission: Preliminary searches.

Conflicts of interest: The authors report no conflicts

of interest in this work.

The effectiveness and safety of Sun's tip-flexible ureterorenoscope for the management of kidney stones: A protocol for systematic review and meta-analysis of randomized controlled trials

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Review question / Objective: P:patients with kidney stones I:Sun's tip-flexible ureterorenoscope C:any management, except Sun's tip-flexible ureterorenoscope O:The primary outcomes is overall stone-free rate. The secondary outcomes are mean stone size (mm), pain intensity, urinary biochemical variables, mean hospital stay (day), quality of life, and adverse events. S: English and Chinese literature about Sun's tipflexible ureterorenoscope treatment for kidney stones published before October 31, 2020 will be systematic searched in PubMed, Embase, Web of Science, Cochrane Library, Open Grey, Clinicaltrials.gov, Chinese Clinical Trial Registry, WANFANG, VIP Chinese Science and Technology Journal Database, CNKI, Chinese biomedical document service system(SinoMed). Only RCTs of patients with kidney stones will be included. Literature screening, data extraction, and the assessment of risk of bias will be independently conducted by 2 reviewers, and the 3rd reviewer will be consulted if any different opinions existed. Systematic review and meta-analysis will be produced by RevMan 5.3 and Stata 14.0. This protocol reported in accordance with the Preferred Reporting Items for Systematic Review and Meta-analysis Protocols (PRISMA-P) statement, and we will report the systematic review by following the PRISMA statement.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 23 November 2020 and was last updated on 23 November 2020 (registration number INPLASY2020110099).

INTRODUCTION

Review question / Objective: P:patients with kidney stones I:Sun's tip-flexible ureterorenoscope C:any management, except Sun's tip-flexible ureterorenoscope O:The primary outcomes is overall stonefree rate. The secondary outcomes are

mean stone size (mm), pain intensity, urinary biochemical variables, mean hospital stay (day), quality of life, and adverse events. S: English and Chinese literature about Sun's tip-flexible ureterorenoscope treatment for kidney stones published before October 31, 2020 will be systematic searched in PubMed, Embase, Web of Science, Cochrane Library, Open Grey, Clinicaltrials.gov, Chinese Clinical Trial Registry, WANFANG, VIP **Chinese Science and Technology Journal** Database, CNKI, Chinese biomedical document service system(SinoMed). Only RCTs of patients with kidney stones will be included. Literature screening, data extraction, and the assessment of risk of bias will be independently conducted by 2 reviewers, and the 3rd reviewer will be consulted if any different opinions existed. Systematic review and meta-analysis will be produced by RevMan 5.3 and Stata 14.0. This protocol reported in accordance with the Preferred Reporting Items for Systematic Review and Meta-analysis Protocols (PRISMA-P) statement, and we will report the systematic review by following the PRISMA statement.

Condition being studied: Kidney stone is one of the urinary system diseases with a high incidence.

METHODS

Participant or population: patients with kidney stones.

Intervention: Sun's tip-flexible ureterorenoscope.

Comparator: Any management, except Sun's tip-flexible ureterorenoscope.

Study designs to be included: Only RCTs of patients with kidney stones will be included.

Eligibility criteria: This study will include only RCTs.All included participants must be diagnosed with KS, regardless of country, ethnic background, gender, age, and economic status. Any forms of Sun's tipflexible ureterorenoscope intervention alone has been assigned to the patients in the experimental group. The intervention in the control group could be any management, except Sun's tip-flexible ureterorenoscope.

Information sources: English and Chinese literature about Sun's tip-flexible ureterorenoscope treatment for kidney stones published before October 31, 2020 will be systematic searched in PubMed, Embase, Web of Science, Cochrane Library, Open Grey, Clinicaltrials.gov, Chinese Clinical Trial Registry, WANFANG, VIP Chinese Science and Technology Journal Database, CNKI, Chinese biomedical document service system(SinoMed).

Main outcome(s): The primary outcomes is overall stone-free rate.

Quality assessment / Risk of bias analysis: Two researchers will evaluate the risk of bias for all included RCTs using Cochrane Risk of Bias Tool. We will assess each study at 7 levels, and each one is divided into 3 degrees: low, unclear, and high risk of bias. The differences between two researchers will be solved by consensus via discussion.

Strategy of data synthesis: We will perform a systematic narrative synthesis to summarize and explain the characteristics and findings of the included studies and provide this information in the text and tables. Review Manager 5.3 provided by the Cochrane Collaboration will be used for the meta-analysis (If feasible), and the randomeffects model will be chosen to combine all summary outcome measures. If a metaanalysis is impossible, the results of clinical trial comparisons will be analyzed descriptively. Dichotomous outcomes (e.g. effective and ineffective) will be determined by relative risk (RR) with 95% confidence interval (CI), while continuous data will be analyzed using weighted mean difference (if measurement methods are consistent) or standardized mean difference (if measurement methods are different).

Subgroup analysis: When there is obvious heterogeneity among included studies, we

will perform a subgroup analysis in accordance with different study qualities, treatments, controls, and outcome measurements.

Sensibility analysis: We will also use sensitivity analysis to test the stability and reliability of meta-analysis. It will be conducted by 2 methods: eliminating each study one by one; using random-effect model (DerSimonian & Laird method) to test the results after using the fixed effect model.

Country(ies) involved: China.

Keywords: Sun's tip-flexible ureterorenoscope, kidney stones, metaanalysis, systematic review.

Contributions of each author:

Author 1 - Yuecai Yuan. Author 2 - Rui Zhong. Author 3 - Liang Zhong. Author 4 - Haibiao Lai. Author 5 - Zhifeng Huang. Author 6 - Ye Zeng. Author 7 - Song Wu.