INPLASY PROTOCOL

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None declared.

Current update of effectiveness and safety of selective serotonin reuptake inhibitors (SSRIs) treatment of premenstrual dysphoric disorder (2011-2021): A protocol for systematic review and meta-analysis

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Review question / Objective: **To update of effectiveness and safety of selective serotonin reuptake inhibitors (SSRIs) treatment of premenstrual dysphoric disorder.**
Condition being studied: **Premenstrual disorders of women has become more prevalent across the globe. Although selective serotonin-reuptake inhibitors (SSRIs) have been used in clinic as first-line therapy for premenstrual dysphoric disorder (PMDD), there still is a lack of systematic efficacy evaluation, especially the diversification of pathogenic factors in recent years.**
Information sources: **Medline, Embase and Cochrane Central Register of Controlled Trials will be been comprehensive searched. Given that SSRIs is widely used in China, we will search the following Chinese databases: China National Knowledge Infrastructure, Chinese scientific periodical database of VIP INFORMATION and Wanfang Data from May 1st, 2011 to May 1st, 2021. The search strategy for PubMed is as follows (Table1). And the equivalent search words will be used in other databases as well.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 01 May 2021 and was last updated on 01 May 2021 (registration number INPLASY202150003).

INTRODUCTION

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selective serotonin-reuptake inhibitors (SSRIs) have been used in clinic as first-line therapy for premenstrual dysphoric disorder (PMDD), there still is a lack of systematic efficacy evaluation, especially the diversification of pathogenic factors in recent years.

METHODS

Search strategy: Eight electronic databases (Science Citation Index, PubMed Database, Embase Database, the Cochrane Central Register of Controlled Trials, Chinese BioMedical Database, China National Knowledge Infrastructure, Wanfang database and the Chongqing VIP Chinese Science and Technology Periodical Database) will be searched from May 1st, 2011 to May 1st, 2021.

Participant or population: Women of reproductive age diagnosed with premenstrual dysphoric disorder will be included. Our review included studies using DSM (III, IV, IV-R, V). There will be no restrictions in terms of the patients' age, gender, race, education or economic status.

Intervention: The study was a double-blind, randomized, controlled trial of an SSRIs compared with placebo and the study examined an SSRIs at any dose and any dosing regimen for more than one menstrual cycle compared with placebo. The study had to report change in overall premenstrual symptomatology as measured by a validated.

Comparator: Placebo.

Study designs to be included: RCTs with or without blinding will be included in this study. Non-RCTs, studies with the cross-over design, and uncontrolled clinical trials will be excluded.

Eligibility criteria: Inclusion and exclusion criteria are categorized by population, interventions, comparators, outcomes and study design (PICOS). The year of publication is restricted from 2011-2021 and there were no restrictions regarding the language of the article.

Information sources: Medline, Embase and Cochrane Central Register of Controlled Trials will be been comprehensive searched. Given that SSRIs is widely used in China, we will search the following Chinese databases: China National Knowledge Infrastructure, Chinese scientific periodical database of VIP INFORMATION and Wanfang Data from May 1st, 2011 to May 1st, 2021. The search strategy for PubMed is as follows (Table1). And the equivalent search words will be used in other databases as well.

Main outcome(s): The main outcome measure was a reduction in overall premenstrual syndrome symptoms, such as emotional symptoms, somatic symptoms and functional improvement. Where individual symptoms were presented then these were combined to give an overall score. Combined or overall scores of global premenstrual syndrome measures were chosen in an attempt to overcome the clinical heterogeneity associated with the measurement and scoring of premenstrual syndrome symptoms used in individual trials.

Data management: Two review authors will independently extract data on methods, patients, interventions, outcomes and results from the included studies, using a preformulated data collection form.

Quality assessment / Risk of bias analysis: The quality of each trial was assessed using a scale developed by Jadad scale, which assesses the randomization, double blinding and reports of dropouts and withdrawals for the trials. Disagreements will be resolved by discussion or by involving another reviewer.

Strategy of data synthesis: We conducted meta-analyses of studies on the use of SSRIs for the treatment of premenstrual dysphoric disorder using DerSimonian-Laird random-effects models to compute summary risk ratios with 95% confidence intervals. All analyses were conducted with

the Stata/SE 15.1 (Stata-Corp LP, College Station, TX) using the "metan" command. Both random effects and fixed effects models were computed, but with no significant differences between the two, only random effects results are presented.

Subgroup analysis: A priori defined subgroup analyses by dosing regimen (intermittent compared with continuous, symptomatic dosing compared with standard dosing), SSRI type, and year of publication were conducted.

Sensitivity analysis: Sensitivity analyses will be conducted to examine the overall effect size of the primary outcome measurement while temporarily removing: (1) each study individually from the meta-analysis, (2) studies with sample sizes ≤20 across conditions, (3) studies with attrition rates≥30% in at least one trial arm, and (4) studies in each rating category of overall risk of bias (ie, high- moderate- respectively low risk of bias).

Country(ies) involved: China.

Keywords: SSRIs, premenstrual dysphoric disorder, meta-analysis, systematic review, protocol.

Dissemination plans: The results of this study will be published in peer-reviewed journals.

Contributions of each author:

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