INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Is fluoxetine necessary for preventive treatment of post-stroke depression in stroke patients? A meta-analysis of randomized controlled trials

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Review question / Objective: **One third of patients may have post-stroke depression after a stroke. Poststroke depression seriously affects rehabilitation outcome, quality of life and mortality of stroke patients. Data on preventive treatment of fluoxetine for post-stroke depression in this setting are inconsistent. The purpose of this systematic review was to explore the efficacy and acceptability of fluoxetine for early antidepressant therapy in stroke patients, so as to better provide evidence-based medical evidence for clinical practice. To this end, the systematic review to be considered will address the following issues: P: stroke patients; I: Treatment interventions included: fluoxetine (Prozac), control group: conventional treatment, plus placebo or no other intervention; O: Primary outcome: incidence of PSD, secondary outcome: Hamilton Scale, neurological dysfunction, daily living ability, mortality, incidence of adverse reactions; S: This review includes only randomized controlled studies.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 March 2022 and was last updated on 24 March 2022 (registration number INPLASY202230137).

INTRODUCTION

Review question / Objective: **One third of patients may have post-stroke depression after a stroke. Poststroke depression seriously affects rehabilitation outcome, quality of life and mortality of stroke patients. Data on preventive treatment of fluoxetine for post-stroke depression in this setting are inconsistent. The purpose of this systematic review was to explore the efficacy and acceptability of fluoxetine**

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Condition being studied: Fluoxetine is a selective inhibitor of serotonin reuptake and is widely used to treat depression. Fluoxetine has been used as an antidepressant in patients with acute stroke in a growing number of studies. However, conformance between guan and fluoxetine in the prevention and acceptability of stroke patients has not been reached. In this study, we will conduct a meta-analysis to evaluate the preventive efficacy and safety of fluoxetine in stroke patients, and the results will be helpful for clinical decision making.

METHODS

Search strategy: The databases searched included PubMed, Embase, Cochrane Library, China National Knowledge Infrastructure, China Biomedical Literature Service System, Wanfang Database and VIP database. The time frame of the search was from the establishment of the database to April 2022. A combination of free words and subject words is used in the search process. Search terms included "fluoxetine," "Prozac," "stroke," "prevention," "post-stroke depression," and "depression."

Participant or population: Stroke patients.

Intervention: Treatment interventions included: fluoxetine (Prozac), control group: conventional treatment, plus placebo or no other intervention.

Comparator: Fluoxetine versus placebo.

Study designs to be included: The study was designed to include all randomized controlled trials that met the requirements.

Eligibility criteria: A randomized controlled study of all fluoxetine prophylactic therapy in stroke patients, regardless of blinding.A randomized controlled study of fluoxetine prophylaxis in all stroke patients, regardless of blindness, regardless of country, language, or race.

Information sources: Our study will search the following electronic databases: PubMed, EMBASE, Cochrane Library, China National Knowledge Infrastructure (CNKI), VIP Database, Wanfang Database and China Biomedical Literature Database, randomized controlled trials (RCTS) related to preventive treatment of fluoxetine in stroke patients.

Main outcome(s): Preventive efficacy of PSD: including the incidence of PSD and the Hamilton Depression Scale.

Additional outcome(s): Neurological dysfunction, activities of daily living, mortality, incidence of adverse reactions.

Quality assessment / Risk of bias analysis: The two reviewers conducted a rigorous methodological quality assessment of the methodological characteristics of the included studies by referring to the Cochrane Collaborative Bias Risk Assessment tool.

Strategy of data synthesis: Meta-analysis was performed using RevMan 5.3 software. The included studies were tested for heterogeneity, and the x2 test was used for analysis (the test level was α=0.1). The degree of heterogeneity was quantitatively judged by combining with I2. I20.1 indicate a small heterogeneity, and the fixed effects model is adopted. I2≥50% and p≤0.1 indicate a large heterogeneity, and the random effects model is used for analysis. When the measurement tool and unit of the continuous variable are the same, the standardized mean difference (SMD) is used. When the measurement tools or units

of continuous variables are not the same, the weighted average difference is used. The risk ratio (RR) is used as the effect analysis statistic for binary variables. All effect sizes are provided with 95% confidence intervals (95% CI). If the required research data are not reported in the study, the researcher will contact the original author via phone or email to obtain additional information. If the required research data are not available, we will use descriptive analysis or exclude these studies when necessary.

Subgroup analysis: Subgroup analyses will be performed to look for potential inconsistencies and heterogeneity, such as fluoxetine duration.Subgroup analyses will be performed to look for potential inconsistencies and heterogeneity, such as duration of fluoxetine use.

Sensitivity analysis: Sensitivity analysis will be performed to verify the robustness of the results. Studies with high risk bias risk will be excluded and the stability and reliability of the conclusions drawn from the meta-analysis will be ensured.

Language: No restriction.

Country(ies) involved: China.

Keywords: Fluoxetine, stroke, prevention, post-stroke depression, meta-analysis.

Contributions of each author:

Author 1 - Dou Wang - The authors drafted the manuscript and completed the bias risk assessmentThe author drafted the manuscript.
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