INPLASY PROTOCOL

To cite: Qiu et al. Efficacy and Tolerability of Zuranolone in Patients with Depression: A Meta-analysis of Randomized controlled trials. Inplasy protocol 202350104. doi: 10.37766/inplasy2023.5.0104

Received: 28 May 2023

Published: 28 May 2023

Corresponding author:
Youjia Qiu

qiu_youjia@163.com

Author Affiliation:
First Affiliated Hospital of Soochow University.

Support: **Grant from Suzhou Government (SYS2019045).**

Review Stage at time of this submission: **Completed but not published.**

Conflicts of interest:
None declared.

Efficacy and Tolerability of Zuranolone in Patients with Depression: A Meta-analysis of Randomized controlled trials

Qiu, YJ[1]; Tao, YC[2]; Duan, AJ[3]; Wei, XZ[4]; Wang, MH[5]; Xie, MJ[6]; Chen, ZQ[7]; Shang, J[8]; Wang, Z[9]; Chen, G[10].

Review question / Objective: **(a) population: patients diagnosed as major depressive disorder or postpartum depression according to standard diagnostic criteria; (b) intervention: patients received zuranolone were considered intervention group; (c) comparison: patients received placebo were considered comparsion group; (d) outcome: the primary outcome was the change of depressive severity scores. Secondary efficacy outcomes included response and remission after the treatment; safety outcomes were adverse events; (e) study design: only randomized controlled trials were included.**
Eligibility criteria: **Studies meet with one of the following criteria were excluded: (1) study type: cohort study, case reports, review, letter; (2) language: non-English article; (4) lack of depression measurement results.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 28 May 2023 and was last updated on 28 May 2023 (registration number INPLASY202350104).

INTRODUCTION

Review question / Objective: **(a) population: patients diagnosed as major depressive disorder or postpartum depression according to standard diagnostic criteria; (b) intervention: patients received zuranolone were considered intervention group; (c) comparison: patients received placebo were considered comparsion group; (d) outcome: the primary outcome was the change of depressive severity scores. Secondary efficacy outcomes included response and remission after the treatment; safety outcomes were adverse events; (e) study design: only randomized controlled trials were included.**

Condition being studied: **Depression is a chronic mental disorder with high prevalence, which may also result in**

increased suicide rates. Major depressive disorder is the most common type of depression globally. In addition, some people were prone to come up with depression, such as female and the elderly. Pregnant women who have depression is considered postpartum depression. Although many treatments have been advocated to treat major depressive disorder and postpartum depression, traditional antidepressant treatment demonstrated lower response and higher recurrence rates. Therefore, novel antidepressant drugs for MDD and PPD is required. Zuranolone is a GABAA receptors drug which resembles brexanolone. Several finished or ongoing clinical trials endeavor to explore its antidepressant effects in depression. Therefore, we conducted a meta-analysis to comprehensively evaluate its effectiveness in treating depression.

METHODS

Participant or population: Patients diagnosed as MDD or PPD based on currently acknowledged guidelines.

Intervention: Patients who were treated by zuranolone.

Comparator: Patients who were treated by placebo.

Study designs to be included: The study design includes randomized controlled trials.

Eligibility criteria: Studies meet with one of the following criteria were excluded: (1) study type: cohort study, case reports, review, letter; (2) language: non-English article; (4) lack of depression measurement results.

Information sources: Electronic database such as PubMed, Embase, and Cocrahne Library were used to extract eligible studies.

Main outcome(s): The main outcome is the change of depressive severity score evaluated by commonly used rating scale.

Quality assessment / Risk of bias analysis: Risk of bias was evaluated using Cochrane Collaboration tool.

Strategy of data synthesis: Dichotomous and continuous variables were expressed as risk ratio and mean difference. The Cochran Q test and I2 test were used to analysis the heterogeneity. When heterogenity was high, we perform sensitive analysis, subgroup analysis, and meta regression to detect the source of heterogeneity. $P < 0.05$ indicates statistically significant in all analysis. Review Manager was used for statistical analysis in this study.

Subgroup analysis: Subgroup anlaysis was performed on different dose of zuranolone and different types of depression.

Sensitivity analysis: Sensitivity analysis was performed to detect the source of heterogeneity.

Language restriction: English.

Country(ies) involved: China.

Keywords: Depression, Major depressive disorder, postpartum depression, zuranolone, meta-analysis.

Contributions of each author:
Author 1 - Youjia Qiu.
Email: qiu_youjia@163.com
Author 2 - YuChen Tao.
Email: 1290581452@qq.com
Author 3 - Aojie Duan.
Email: d362922899@163.com
Author 4 - Xingzhou Wei.
Email: wxzhou1124@163.com
Author 5 - Menghan Wang.
Email: 1307068662@qq.com
Author 6 - Minjia Xie.
Email: xieminjia666@163.com
Author 7 - Zhouqing Chen.
Email: zqchen6@163.com
Author 8 - Jing Shang.
Email: wxzhou1124@163.com
Author 9 - Zhong Wang.
Email: wangz8761@163.com