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The Psychotropic Effects of Levetiracetam: A Systematic Review and Meta-Analysis of Randomized Comparator-Controlled Trials Using Various Psychological and Psychiatric Instruments

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Data analysis.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY2024120028

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 8 December 2024 and was last updated on 8 December 2024.

INTRODUCTION

Review question / Objective To investigate the psychotropic effects of levetiracetam by systematically reviewing and analyzing randomized controlled trials that utilize psychological and psychiatric instruments.

Rationale Levetiracetam has been linked to negative psychotropic effects such as aggression, anxiety, and depression. Despite these findings, there is a lack of robust, high-quality evidence from diverse assessment tools. This study aims to systematically assess levetiracetam's psychotropic effects across various domains.

Condition being studied Psychotropic effects, including psychological and psychiatric symptoms associated with levetiracetam use.

METHODS

Search strategy Keywords include: levetiracetam, behavioral symptoms, behavior, anxiety, depressive, depression, mania, anger, hostility, aggression, irritability, psychiatric, cognitive, mood, schizophrenia, schizophrenic, score, scale, inventory, questionnaire, interview, profile, instrument, checklist, randomized, randomised. Databases: PubMed, Cochrane CENTRAL, Web of Science.

Participant or population Human subjects.

Intervention Levetiracetam.

Comparator Other treatments or placebo.

Study designs to be included Randomized controlled trials (RCTs).

Eligibility criteria
Inclusion Criteria:
1. RCTs with human subjects.
2. Studies measuring psychological or psychiatric instrument outcomes for levetiracetam and comparators.
•Exclusion Criteria:

1. Studies without a comparator group.
2. Studies lacking quantitative outcomes.

Information sources Systematic searches in PubMed, Cochrane CENTRAL, and Web of Science. References of relevant articles will also be examined.

Main outcome(s) Primary outcomes include changes in psychological or psychiatric scores, including global mood, aggression, anger, anxiety, depression, and schizophrenia-related scales.

Additional outcome(s) Secondary outcomes include withdrawal rates and specific withdrawal events due to psychotropic effects.

Data management Two independent reviewers will extract study data. Missing data will be obtained from corresponding authors when possible.

Quality assessment / Risk of bias analysis The Cochrane Risk of Bias Tool (RoB 2) will be used, evaluating domains including randomization, intervention adherence, missing outcome data, outcome measurement, selective reporting, period and carryover effects (if applicable), and overall risk of bias.

Strategy of data synthesis Intention-to-treat (ITT) analysis will be employed. Odds ratios (ORs) and their 95% confidence intervals will be calculated. Heterogeneity will be assessed using I^2 statistics.

Subgroup analysis Analyses will consider factors such as the type of comparator, patient population (epilepsy vs. non-epilepsy), treatment modality (monotherapy vs. adjunctive therapy), and variations in dosage.

Sensitivity analysis Sensitivity analysis will involve systematically excluding one study at a time to assess robustness.

Language restriction No language restrictions.

Country(ies) involved Taiwan.

Other relevant information Not applicable.

Keywords Levetiracetam; psychotropic; psychiatric; psychological; clinical trials; systematic review; meta-analysis.

Dissemination plans Results will be disseminated via peer-reviewed journals and academic conferences.

Contributions of each author

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