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Efficacy and safety of SPN-812 (extended-release viloxazine) in children and adolescents with attention-deficit/hyperactivity disorder: a systematic review and meta-analysis

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ADMINISTRATIVE INFORMATION

Support - Suzhou Health Talents Training Project (GSWS2019002) and Gusu Project, Gusu College, Nanjing Medical University (GSKY20210207).

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

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 16 September 2023 and was last updated on 16 September 2023.

INTRODUCTION

Review question / Objective P:children and adolescents with ADHD; I:SPN-812; C:placebo; O:ADHD-RS-5, Conners 3-PS, WFIRS-P, CGI-I score, AEs and SAEs; S:RCTs.

Condition being studied ADHD (attention deficit hyperactivity disorder) is a widespread and debilitating neuropsychiatric condition that affects children and teenagers.

METHODS

Participant or population Children and adolescents (6-17 years old) who were diagnosed with ADHD.

Intervention Different doses of SPN-812 vs. placebo.

Comparator ADHD-RS-5, Conners 3-PS, WFIRS-P, CGI-I score, AEs and SAEs.

Study designs to be included Randomized controlled trials.

Eligibility criteria Inclusion criteria :(1) The type of study must be an RCT; (2) language: English (3) Subjects: diagnosed ADHD patients (6-17 years old); (4) intervention: different doses of SPN-812 and placebo; (5) Indicators: ADHD-RS-5, Conners 3-PS, WFIRS-P, CGI-I score, AEs and SAEs. Case reports, case reviews, retrospective studies, and cohort studies and studies with active controls were excluded.

Information sources Four electronic databases.

Main outcome(s) SPN-812(100, 200, 400 mg/d) is superior to the corresponding control in terms of efficacy indicators.

Quality assessment / Risk of bias analysis

Review Manager 5.3 software was used to assess the risk of bias.

Strategy of data synthesis SPN-812'/exp AND `attention-deficit/hyperactivity disorder'/exp was searched for EMBASE; (attention-deficit/hyperactivity disorder [Title/Abstract]) AND (SPN-812[Title/Abstract])were searched for MEDLINE; "SPN-812 | attention-deficit/hyperactivity disorder"was searched from Clinicaltrials.gov; and "SPN-812" in Title Abstract Keyword AND "attention-deficit/hyperactivity disorder" in Title Abstract Keyword for Cochrane Library.

Subgroup analysis The patients were divided into different age groups at baseline for subgroup analysis.

Sensitivity analysis Sensitivity analysis is used to assess the stability of the consolidate results.

Country(ies) involved China.

Keywords SPN-812, pediatric patients, ADHD.

Contributions of each author

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