International Platform of Registered Systematic Review and Meta-analysis Protocols

INPLASY

Safety of Eptinezumab in the treatment of migraine: a updated systematic review and meta-analysis

INPLASY202510104
doi: 10.37766/inplasy2025.1.0104
Received: 25 January 2025
Published: 25 January 2025

Chen, JC; Li, Y; Luo, C; Huang, SQ; Chen, YS.

Corresponding author:
Junchen Chen

616548275@qq.com

Author Affiliation:
The First Affiliated Hospital of Shantou University Medical College.

ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - The review has not yet started.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202510104

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 25 January 2025 and was last updated on 25 January 2025.

INTRODUCTION

Review question / Objective Eptinezumab, a humanized monoclonal antibody targeting calcitonin gene-related peptide (CGRP), prevents both episodic and chronic migraines. Understanding the adverse events linked to eptinezumab, is essential for their safe and effective use. This systematic review and meta-analysis aims to assess the safety of administering eptinezumab versus a placebo in patients with migraines.

Condition being studied Eptinezumab, a humanized monoclonal antibody targeting calcitonin gene-related peptide (CGRP), prevents both episodic and chronic migraines. Understanding the adverse events linked to eptinezumab, is essential for their safe and effective use.

METHODS

Participant or population Participants eligible for inclusion are adults of any gender, aged 18 or older, with a diagnosis or history of episodic or chronic migraines.

Intervention Eptinezumab, any dose and duration of treatment.

Comparator Placebo treatment.

Study designs to be included Randomized controlled trials.

Eligibility criteria Inclusion Criteria：Randomized controlled trials from Phase 2, Phase 3, and Phase 4 will be considered eligible for inclusion.
Exclusion Criteria：Extremely small sample size. Studies conducted on animal models,

observational studies, case reports, review articles, and conference abstracts will be excluded.

Information sources Pubmed, Embase, Cochrane, Web of Science and US National Institutes of Health Clinical Trials Registry etc.

Main outcome(s) Adverse events , including treatment-related adverse events and serious adverse events.

Data management Endnote, Revman and Stata.

Quality assessment / Risk of bias analysis Cochrane TOOL.

Strategy of data synthesis Data synthesis will be conducted using RevMan (Review Manager 5.4). For dichotomous outcomes, relative risks (RR) with 95% confidence intervals (95% CI) will be reported, while for continuous outcomes, the mean difference (MD) or standardized mean difference (SMD) with corresponding 95% CIs will be calculated. A random-effects model will be employed to pool the data from the included studies. Heterogeneity among the trials will be assessed using the Chi-squared test and the I^2 statistic. A random-effects model will be applied for data analysis, and heterogeneity will be considered significant if I^2 exceeds 50%. Additionally, subgroup analyses will be performed based on different dosage levels of the intervention.

Subgroup analysis Subgroup analyses will be performed to investigate the adverse effects of eptinezumab in different patient populations, based on gender and age, dosage levels.

Sensitivity analysis To evaluate the influence of various factors or methodological decisions on the primary results of our study, a sensitivity analysis will be conducted. This analysis will follow three approaches: first, including only studies with a low risk of bias; second, using fixed-effects models to examine the impact of the chosen statistical model on the outcomes; and third, applying the Paule-Mandel estimator for Tau^2 and the Hartung-Knapp adjustment for confidence intervals to assess the robustness of the results.

Country(ies) involved China.

Keywords Eptinezumab; Migraine; Adverse Events; Safety.

Contributions of each author

Author 1 - Junchen Chen.
Author 2 - Yong Li.
Author 3 - Cheng Luo.
Author 4 - Shunqiu Huang.
Author 5 - Yashi Chen.