INPLASY PROTOCOL

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Review Stage at time of this submission: **Preliminary searches.**

Conflicts of interest:
None declared.

The neuroprotective effect of edaravone dexborneol in cerebrovascular disease: a comprehensive systematic review and meta-analysis

Chen, Q[1]; Wang, Q[2].

Review question / Objective: **P: Patients with cerebrovascular disease; I: Intervention with edaravone dexborneol; C: Intervention with other drugs or placebo ; O: outcomes for effective rate, adverse events, neurological behaviour scale (NIHSS, mRS, BI), inflammatory factors (CRP, hs-CRP, TNF-α, MMP-9), oxidative stress factors (MDA, SOD, ROS, NE) S: RCTs.**
Condition being studied: **For edaravone dexborneol in acute ischemic stroke, the phase II clinical trial reported that edaravone Dexborneol was safe and well tolerated at all doses, although no significant improvement in functional outcomes was observed at 90days. Phase III clinical trial reported that 90-day good functional outcomes favored the edaravone dexborneol group compared with edaravone , especially in female patients.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 November 2022 and was last updated on 15 November 2022 (registration number INPLASY2022110069).

INTRODUCTION

Review question / Objective: **P: Patients with cerebrovascular disease; I: Intervention with edaravone dexborneol; C: Intervention with other drugs or placebo ; O: outcomes for effective rate, adverse events, neurological behaviour scale (NIHSS, mRS, BI), inflammatory factors (CRP, hs-CRP, TNF-α, MMP-9), oxidative stress factors (MDA, SOD, ROS, NE) S: RCTs.**

Rationale: **The incidence of cerebrovascular diseases is increasing every year, edaravone dexborneol as a**

novel neuroprotective agent that comprises edaravone and (+)-borneol in a 4:1 ratio has been used for cerebrovascular diseases in China. It is urgent to know accurately the neuroprotection of edaravone dexborneol in cerebrovascular diseases.

Condition being studied: For edaravone dexborneol in acute ischemic stroke, the phase II clinical trial reported that edaravone Dexborneol was safe and well tolerated at all doses, although no significant improvement in functional outcomes was observed at 90days. Phase III clinical trial reported that 90-day good functional outcomes favored the edaravone dexborneol group compared with edaravone , especially in female patients.

METHODS

Search strategy: Two researchers searched Chinese databases (Zhi Wang, Wan Fang, VIP, CBM, DUXIU) and English databases (PubMed, Ovid-medline, Cochrane Library) (Edaravone dexborneol) AND (Embolic Stroke/ OR Heat Stroke/ OR Hemorrhagic Stroke/ OR Ischemic Stroke/ OR "National Institute of Neurological Disorders and Stroke (U.S.)"/ OR Stroke/ OR Stroke, Lacunar/ OR Stroke Rehabilitation/ OR Stroke Volume/ OR Thrombotic Stroke/) AND ("Randomized Controlled Trials as Topic") .

Participant or population: Patients must be over 18 years old; sample size is not less than 20; conformed to the diagnostic criteria of the sixth Congress of Chinese Cerebrovascular Diseases or the World Health Organization (WHO). Hemorrhagic stroke had to be excluded based on Craniocerebral Computerized Tomography or Magnetic Resonance Imaging

Intervention: Intervention with edaravone dexborneol for 14d or 28d.

Comparator: Intervention with other drugs or placebo.

Study designs to be included: RCTs.

Eligibility criteria: Inclusion criteria (1. Experiment must be a RCT; 2.Participants were older than 18 years old) exclusion criteria (1.The sample size was less than 20; 2. Other related treatments were performed prior to the intervention).

Information sources: Chinese databases (Zhi Wang, Wan Fang, VIP, CBM, DUXIU) and English databases (PubMed, Ovid-medline, Embase, Cochrane Library).

Main outcome(s): Effective rate, adverse events, neurological behaviour scale (NIHSS, mRS, BI), inflammatory factors (CRP, hs-CRP, TNF-α, MMP-9), oxidative stress factors (MDA, SOD, ROS, NE).

Data management: ENDNote 20.

Quality assessment / Risk of bias analysis: Cochrane Tool.

Strategy of data synthesis: When the data is heterogeneous, random effects are selected to merge the data. When the data is not heterogeneous, fixed effects are selected to merge the data.

Subgroup analysis: Subgroup analysis is performed according to factors such as types of cerebrovascular disease and ages of patients.

Sensitivity analysis: After deleting any one of the documents, the combined results of the remaining documents are not much different from those without deletion, which means that the sensitivity analysis has passed.

Language restriction: Chinese or English.

Country(ies) involved: China.

Keywords: Edaravone dexborneol, cerebrovascular diseases.

Contributions of each author:
Author 1 - Chen Qian - Author 1 collects related studies from electronic databases and drafts the manuscript.

Author 2 - Wang Qinhao - Author 2 extracts main outcomes from all related studies and make a consolidation analysis by Rv.Man software.
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