INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Outcomes of therapeutic hypothermia combined with decompressive craniectomy for malignant middle cerebral artery infarction: A systematic review and meta-analysis

Wu, J[1]; Wang, Z[2]; Feng, Y[3]; Zhang, C[4].

Review question / Objective: **Compared with decompressive craniectomy, what is the effect of therapeutic hypothermia combined with decompressive craniectomy on the survival and prognosis of patients with malignant middle cerebral artery infarction.**
Condition being studied: **The mortality of untreated patients with Malignant Middle Cerebral Artery Infarction(MMCAI) is as high as 80%, and most of the surviving patients have severe neurological dysfunction. Decompressive craniectomy (DC) has been proved to reduce the mortality of patients with MMCAI, but even with the intervention of drugs and surgery, the mortality of patients with MMCA remains at 20% - 30%, There is no unified conclusion about the long-term effect of surgery on neurological function. Hypothermia has a clear protective effect on the brain. Therefore, to evaluate whether TH combined with DC can reduce the mortality and improve the neurological prognosis of patients with MMCAI compared with DC alone.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 July 2021 and was last updated on 24 July 2021 (registration number INPLASY202170075).

INTRODUCTION

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dysfunction. Decompressive craniectomy (DC) has been proved to reduce the mortality of patients with MMCAI, but even with the intervention of drugs and surgery, the mortality of patients with MMCA remains at 20% - 30%, There is no unified conclusion about the long-term effect of surgery on neurological function. Hypothermia has a clear protective effect on the brain. Therefore, to evaluate whether TH combined with DC can reduce the mortality and improve the neurological prognosis of patients with MMCAI compared with DC alone.

METHODS

Participant or population: Patients with MMCAI confirmed by imaging examination.

Intervention: Therapeutic hypothermia combined with decompressive craniectomy.

Comparator: Decompressive craniectomy.

Study designs to be included: We will include randomized controlled trials(RCT) and cohort studies.

Eligibility criteria: Inclusive criteria: (1) participants: Patients with MMCAI confirmed by imaging examination, aged between 18 and 80 years old (2) Intervention measures / control measures: the experimental group was treated with TH combined with DC, while the control group was treated with DC alone (3) outcome measures: main outcome measures: mortality (short-term mortality (follow-up time ≤ 30 days), long-term mortality (follow-up time ≥ 6 months)), secondary outcome measures: good neurological outcome (MRS score ≤ 3 points; Follow up time ≥ 6 months), the included studies must include any one or more outcome indicators (4) Type of study: all clinical studies related to this study, language and publication time are not limited;Exclusion criteria: (1) the types of research included literature review, systematic review, case report, evaluation, reply and non clinical research (2) The literature that can't extract effective outcome indicators (3) Repeated published literature.

Information sources: We will search, with no time restrictions, the following databases for relevant English language literature: PubMed, Embase, Cochrane Library, Web of Science and ClinicalTrials.gov.The search MeSH Terms are: (Infarction, Middle Cerebral Artery), (Decompressive Craniectomy), (Hypothermia). The electronic database search will be supplemented by a manual search of the reference lists of included articles.

Main outcome(s): Mortality(mortality within 30 days and mortality after 6 months).

Additional outcome(s): Good neurological outcome（mRS score ≤ 3，after 6 months).

Quality assessment / Risk of bias analysis: The risk of bias was assessed by two independent researchers. The quality of randomized controlled studies was evaluated using the Cochrane Collaboration's tool ; The quality of cohort studies was evaluated using the Newcastle Ottawa scale (NOS scale) . At the same time, the funnel map was drawn and egger test was performed to further quantitatively evaluate whether the included studies had publication bias.

Strategy of data synthesis: Relative risk (RR) and corresponding 95% confidence interval (95% CI) were used as effect value indicators. We use Cochran Q test to qualitatively evaluate the heterogeneity between studies, and use I2 to quantitatively evaluate the heterogeneity between studies. When I2 > 50%, it is considered that the degree of heterogeneity between studies is high, and when I2 < 50% and Q test p > 0.1, it is considered that there is no heterogeneity. When I2 > 50% or P < 0.1 in Q test, the effect values were combined using random effect model. If I2 < 50% and Q test p > 0.1, the fixed effect model is used to combine the effect values. The forest map

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was used to represent the effect value and combined effect value of each study, and P < 0.05 represented a statistical difference. Statistical analysis and graphic production were performed using Review Manager (version 5.3) and Stata (version 14).

Subgroup analysis: We will consider subgroup such as clinic type or follow-up time.

Sensitivity analysis: When siginificant heterogeneity is observed,senstivity analysis will be uesd to explore sources of heterogeneity.

Country(ies) involved: China.

Keywords: Hypothermia；Decompressive Craniectomy；Infarction, Middle Cerebral Artery；Meta-analysis.

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