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Needle knife treatment of post-stroke spastic hemiparesis : a systematic review protocol

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ADMINISTRATIVE INFORMATION

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Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202390056

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 To evaluate the efficacy and safety of needle knife for post-stroke spastic hemiparesis.

Rationale The mechanism of post-stroke hemiplegic spasticity is not yet very clear to modern medicine, but what is recognised by most researchers is that damage to the central neurons is the underlying cause of spastic paralysis of the limbs.Intracerebral hemorrhage causes damage to central brain function and injury signals are transmitted in the neural net, leading to impairment of centrally controlled peripheral nerve functions.Damage to the conduction pathways between motor areas of the cerebral cortex and upper motor neurons leads to a loss of control of random motor function by higher nerve centres, which is replaced by abnormal spasm-based movement patterns under the control of lower centres.Inhibition of α-motor neurons by higher centres and the cerebral cortex is reduced, then the muscle is overexcited and spasticity occurs.F-wave amplitude was greater on the spastic side than on the healthy side by electromyography.The excitatory signal is amplified through the anterior horn of the spinal cord, and the α-motor neuron cells in the anterior horn of the spinal cord are more excitable.When the patient's local muscle spindle are pulled rapidly, it will induce a tense pulling reflex and a clonic or spasmodic state will appear, which is mostly manifested as an increase in muscle tone of the flexor muscle group of the upper limb and the extensor muscle group of the lower limb.After central injury, the post-activation depression effect are weaken, which reduces α-motor neuron hyperexcitability and inhibits spasticity.When the mechanisms that inhibit excitatory transmission are disrupted, a motor

neurons are excited, and the degree of reduction in post-activation depression effect is positively correlated with the severity of spasticity.Recovery of neurological function in the brain can be achieved by neural remodelling, which is not only dependent on local nerve regeneration but also on effective stimulation of the remaining nerve fibres in the damaged area.Needle knife can achieve effective stimulation of the nerves, increase the degree of sensitisation of the nerves, thereby generating a series of electrophysiological responses and activating the neural plastic mechanism, in order to achieve the purpose of relieving limb spasms after stroke.

Condition being studied Stroke, also known as apoplexy and cerebrovascular accident, is an acute cerebrovascular disease that is the leading cause of death and disability worldwide, including haemorrhagic stroke and ischemic stroke.Of these, ischemic stroke has become the second most common fatal disease in the world.The epidemiological survey showed ischemic stroke accounts for 84.4% of all strokes globally, and the prevalence of ischemic stroke in China is 676.7 per 100,000, which is 3.8 times higher than that of haemorrhagic stroke.With the advancement of society and people's living standards,the mortality rate has been significantly reduced, but the disability rate is still high. Spastic hemiparesis is the main sequelae of stroke recovery, and more than 40% of the patients will have limb dysfunction.This period often lasts for a long time and the progress of rehabilitation is slow, which brings great trouble to clinicians in the treatment of stroke patients during the recovery period and the patients' daily life.

METHODS

Search strategy The following electronic databases will be searched from the respective dates of database inception to September 01, 2023: The CINAHL, China National Knowledge Infrastructure, Cochrane Central Register of Controlled Trials, Allied and Complementary Medicine Database, MEDLINE, Embase, Chinese Biomedical Literature Database, VIP Database, and Wanfang Database.

All published English and Chinese RCTs will be included.

Table 1 Search strategy

No. Search items

#1 MeSH Major Topic: randomized controlled trial

#2 MeSH Major Topic: controlled clinical trial

#3 MeSH Major Topic: randomized

#4 MeSH Major Topic: placebo

#5 MeSH Major Topic: clinical trials

#6 MeSH Major Topic: randomly

#7 MeSH Major Topic: trial

#8 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7

#9 MeSH Major Topic: post-stroke spastic paralysis

#11 MeSH Major Topic: post-stroke hemiplegia with spasticity

#12 MeSH Major Topic: post-stroke limb spasticity

#13 MeSH Major Topic: hemiparesis with spastic post-stroke

#14 MeSH Major Topic: spastic hemiparesis after stroke

#15 MeSH Major Topic: spastic hemiparesis after stroke

#16 MeSH Major Topic: post-stroke spastic paralysis

#17 #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16

#18 MeSH Major Topic: acupotomy

#19 MeSH Major Topic: acupotome

#20 MeSH Major Topic: acupotomology

#21 MeSH Major Topic: needle knife

#22 MeSH Major Topic:needle scalpel

#23 MeSH Major Topic: Small needle knife

#24 MeSH Major Topic:Scalpel treatment

#25 MeSH Major Topic:Xiaozhendao

#26 MeSH Major Topic:stiletto needle

#27 MeSH Major Topic:miniscalpel needle

#28 #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27

#29 #8 and #17 and #28.

Participant or population Subjects had post-stroke spastic hemiparesis independent of gender, ethnic or educational background and financial means and met the following criteria: (1)Patients who meet the diagnostic criteria for cerebral haemorrhage and cranial CT/MRI shows intracerebral haemorrhagic lesions(2)Patients who are between the ages of 30 and 75, have experienced a first episode of cerebral hemorrhage, have had their sickness for more than a week but less than a year, and are experiencing recovery-stage hemiplegic symptoms following a cerebral hemorrhage.(3)Symptoms such as limb paralysis, increased muscle tone, Brunnstrom's stage II-IV (spasticity stage) on the affected limb, modified Ashworth scale grade 1-3.(4)Clearly understand the trial process and sign the informed consent form.(5)Able to actively cooperate with treatment (clear mind, stable condition, fluent speech, no cognitive impairment, etc.)(6)Relatively fixed telephone number and address, which can ensure long-term stable contact and willingness to

accept a longer period of follow-up visits.(7)No use of sedative and anti-spasmodic drugs in the 14 days prior to enrolment.Exclusion criteria(1)Has a serious primary acute or chronic medical or surgical condition.(2)Participated in another clinical trial within 90 days or received another anti-spasticity treatment while the study was ongoing. (3)Simple Intelligence Test (SIT) for those with moderate or higher level of dementia who are unable to follow instructions, express their feelings and co-operate with treatment.(4)Patients with contraindications to needling, e.g. previous allergy to needles, severe needle-sickness, or patients with incomplete skin at the site of application (infection, ulcers, scarring, etc.)(5)Those with severe cardiac, hepatic and renal insufficiency or even shock.(6)Persons with coagulation disorders. (7)Diagnosed with malignant tumour or currently pregnant.

Intervention Subjects had post-stroke spastic hemiparesis independent of gender, ethnic or educational background and financial means and met the following criteria: (1)Patients who meet the diagnostic criteria for cerebral haemorrhage and cranial CT/MRI shows intracerebral haemorrhagic lesions(2)Patients who are between the ages of 30 and 75, have experienced a first episode of cerebral hemorrhage, have had their sickness for more than a week but less than a year, and are experiencing recovery-stage hemiplegic symptoms following a cerebral hemorrhage. (3)Symptoms such as limb paralysis, increased muscle tone, Brunnstrom's stage II-IV (spasticity stage) on the affected limb, modified Ashworth scale grade 1-3.(4)Clearly understand the trial process and sign the informed consent form. (5)Able to actively cooperate with treatment (clear mind, stable condition, fluent speech, no cognitive impairment, etc.)(6)Relatively fixed telephone number and address, which can ensure long-term stable contact and willingness to accept a longer period of follow-up visits.(7)No use of sedative and anti-spasmodic drugs in the 14 days prior to enrolment.Exclusion criteria(1)Has a serious primary acute or chronic medical or surgical condition.(2)Participated in another clinical trial within 90 days or received another anti-spasticity treatment while the study was ongoing.(3)Simple Intelligence Test (SIT) for those.

Comparator The control group will be considered and categorised as follows: 1.Control group (CG) 2.Traditional acupuncture group (TG)3.False acupotomy group (FG) 4.Real acupotomy group (RG) .

Study designs to be included We will assess the research literature based on criteria that examine objectives and participants, interventions, comparisons, outcomes(PICO).If the expression "randomization" is mentioned, we will consider such studies.However, we will rate these studies in the Risk of Bias Assessment if a thorough description of the randomization procedure is not provided.Given to the nature of needle-knife therapy, only single-blind can be considered.In addition, the study will not be included if incorrect randomisation methods are used, such as coin flips.Randomised controlled trials with literature report.

Eligibility criteria We will assess the research literature based on criteria that examine objectives and participants, interventions, comparisons, outcomes(PICO). If the expression "randomization" is mentioned, we will consider such studies. However, we will rate these studies in the Risk of Bias Assessment if a thorough description of the randomization procedure is not provided.Given to the nature of needle-knife therapy, only single-blind can be considered.In addition, the study will not be included if incorrect randomisation methods are used, such as coin flips. Randomised controlled trials with literature reported in Chinese or English will be included, others such as animal testing, uncontrolled trials or case reports will be excluded.

Information sources From the start of the project until September 01, 2023, the following nine databases will be searched: CINAHL, China National Knowledge Infrastructure,Cochrane Central Register of Controlled Trials, Allied and Complementary Medicine Database, MEDLINE, Embase, Chinese Biomedical Literature Database, VIP Database, and Wanfang Database.
The terms will be searched as following: post-stroke spastic hemiparesis, post-stroke spastic paralysis,post-stroke hemiplegia with spasticity,post-stroke limb spasticity, post-stroke limb mobility disorder, post-stroke limb motor dysfunction, post-stroke sequelae, needle knife, needle knife therapy, etc. The MEDLINE search strategy is shown in Table 1. We will use the equivalent search terms in the Chinese database.

Main outcome(s) Modified Ashworth scale, Clinical Spasticity Index (CSI).

Additional outcome(s) Fugl-Meyer Assessment and Manual Muscle Testing (MMT).

Data management Two reviewers (HZH and WZN) double-checked all applicable studies, gathered data, and put it into the RevMan software(V.5.5) .

Predefined data access forms will enter details: list of authors and institutions, source of publication, country, intervention, outcome, adverse impact, etc.Details of needle knife interventions (needle knife model, number of needle feeds, depth of needle feed, angle of needle feed, selected site, etc.) will be elaborated according to the "Standard of the Basic Manipulations of Acupotomy" (ZJ / T D001 - 2014). In case of disagreement, the third reviewer (LZX) will make a decision.

Quality assessment / Risk of bias analysis The risk of bias for each study will be systematically reviews by two independent reviewers (HZH and WZN) using the Cochrane Handbook for the systematic reviews of interventions.Six areas of bias will be assessed, namely selection, performance, detection, attrition, reporting and other sources.For each area, trials will be assessed and rated as low risk, high risk or unclear; where there is uncertainty, the relevant authors will be contacted.Discrepancies will also be arbitrated by the third reviewer (LZX).

Strategy of data synthesis RevMan software (V5.5) will be used to perform data synthesis.The data will be pooled using the random-effects model. If necessary, analyse the possible reasons for the greater degree of heterogeneity or perform subgroup analyses.Meta-analyses were not performed if the heterogeneity of the included trials was large.

Subgroup analysis If data are available, subgroup analysis will be performed. Consider variations in treatment characteristics of needle knife, participant, and control types.And there will be subgroups to account for heterogeneity.

Sensitivity analysis Through a sensitivity analysis, the robustness of the main decisions made during the monitoring review process will be evaluated.During the systematic review process, a number of decision nodes for sensitivity reviews must be taken into account, including methodological flaws, small-scale studies, and missing data.As recommended by the Cochrane Handbook, sensitivity analyses consist of two steps：All significant Meta-analysis research must be included as a first step.In the second step, studies that are known to be eligible.A summary table with the findings of the sensitivity analyses will be presented.As indicated by the results of the sensitivity analyses, the risk of bias will be discussed during the review process.

Language restriction None.

Country(ies) involved China.

Keywords needle-knife; acupotomy;stroke;post-stroke spastic hemiparesis; randomized.

Contributions of each author

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