

# INPLASY PROTOCOL

To cite: Kim et al. External treatment of herbal medicine with Tuina in congenital muscular torticollis : A systematic review and meta-analysis protocol. Inplasy protocol 202210017. doi: 10.37766/inplasy2022.1.0017

Received: 05 January 2022

Published: 05 January 2022

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**Support:** Without financial support.

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

**Conflicts of interest:**  
None declared.

## External treatment of herbal medicine with Tuina in congenital muscular torticollis : A systematic review and meta-analysis protocol

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**Review question / Objective:** By 3 to 4 months of age, infants can keep their necks upright and look into both eyes horizontally. But infants with CMT have a wry neck also known as a twisted neck. Complementary therapies have been commonly used to treat CMT, such as tuina, acupuncture, herbal medicine. Among them, external application of herbal medicine is non-surgical and non-invasive inventions so it can be used widely in East Asia. This review aims to evaluate any form of external application of herbal medicines in CMT, such as cream, oil, extract, form of patch, etc.

**Information sources:** We will electronically search the following database 4 English databases(MEDLINE, PubMed, EMBASE, the Cochrane Central Register of Controlled Trials), 3 Chinese databases(China National Knowledge Infrastructure(CNKI), Chinese Scientific Journal Database(VIP), Wan Fang Database), 4 Korean medical databases(Oriental Medicine Advanced Searching Integrated System(OASIS), Korean Studies Information Service System(KISS), National Digital Science Links(NDSL), Research Information Sharing Service(RISS)) from their founding date to June 2022, without any language restrictions.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 05 January 2022 and was last updated on 17 January 2022 (registration number INPLASY202210017).

## INTRODUCTION

**Review question / Objective:** By 3 to 4 months of age, infants can keep their necks upright and look into both eyes horizontally. But infants with CMT have a

wry neck also known as a twisted neck. Complementary therapies have been commonly used to treat CMT, such as tuina, acupuncture, herbal medicine. Among them, external application of herbal medicine is non-surgical and non-invasive

inventions so it can be used widely in East Asia. This review aims to evaluate any form of external application of herbal medicines in CMT, such as cream, oil, extract, form of patch, etc.

**Condition being studied:** CMT is a common congenital musculoskeletal disease with abnormal head and neck posture caused by the thickness and shortening of the sternocleidomastoid muscle (SCM). CMT can occur due to damage during childbirth or a problem with the posture of the fetus in the uterus, but its pathogenesis remains controversial. Treatment approaches for CMT include manual therapy, infant positioning, exercises therapy, taping, electrical therapy, soft collars, botulinum, and even surgical release. In CAM centered in East Asia, tuina, acupuncture and herbal medicine can be used. Herbal medicine external application is used as a medium during treatment with tuina or in the form of a patch to be pasted. Through percutaneous absorption, not only the efficacy of the herb but also stimulate such as acupuncture points and meridians. And It is also safe, convenient, highly compliant, and cost-effective. For the external application of herbal medicines to CMT in clinical practice, an evidence-based systematic study on the efficacy and safety is needed.

## METHODS

**Participant or population:** Inclusion criteria : 1) Patients must be diagnosed with congenital muscular torticollis 2) Age: Newborn to 2 years old Exclusion criteria: 1) Torticollis caused by other diseases, such as skeletal torticollis, compensatory torticollis caused by atlantoaxial joint subluxation, visual impairment, hearing impairment, and neurotic torticollis caused by cervical muscle paralysis. 2) Those who have major organ function deterioration and complications such as heart, liver, kidney, etc.

**Intervention:** The interventions of the experimental group will include tuina with any type of external application of traditional herbal medicine, with no

limitation of the number of herbs, the formations(e.g., ointment, spray, powder or decoction), dosages, or duration of the interventions. We excluded studies that external application with heat stimulation or steam fumigation. Tuina includes Chinese massage, manipulation, therapeutic massage, general massage and relaxation, etc.

**Comparator:** The controlled intervention accepts the same tuina therapy as the experimental group.

**Study designs to be included:** All the published RCTs of external application Herbal Medicines for CMT will be included.

**Eligibility criteria:** Non-RCTs, RCT protocol, animal studies, case reports, survey and reviews were excluded.

**Information sources:** We will electronically search the following database 4 English databases(MEDLINE, PubMed, EMBASE, the Cochrane Central Register of Controlled Trials), 3 Chinese databases(China National Knowledge Infrastructure(CNKI), Chinese Scientific Journal Database(VIP), Wan Fang Database), 4 Korean medical databases(Oriental Medicine Advanced Searching Integrated System(OASIS), Korean Studies Information Service System(KISS), National Digital Science Links(NDSL), Research Information Sharing Service(RISS)) from their founding date to June 2022, without any language restrictions.

**Main outcome(s):** 1) TER( total effective rate); 2) Thickness of the SCM mass; 3) Range of neck motion.

**Additional outcome(s):** 1) symptom scores 2) relapse rates 3) adverse effects.

**Quality assessment / Risk of bias analysis:** Quality assessment will be performed using Risk of bias(Rob) from the Cochrane Handbook for Systematic reviews of Interventions, which include sequence generation, allocation concealment, blinding, incomplete outcome data,

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selective outcome reporting and other sources of bias. The reviewers will summarize the assessments, and categorize the included studies into three levels of bias (low, unclear and high risk of bias).

**Strategy of data synthesis:** Two authors will independently synthesize the data by Review Manager 5.4 software. For the dichotomous outcomes, data will be summarized using Risk Ratio (RR) with 95% Confidence Intervals (CI). For continuous outcomes, a standard mean difference (SMD) with 95% CI will be used.

**Subgroup analysis:** Subgroups analysis would be performed if meta-analysis shows significant heterogeneity.

**Sensitivity analysis:** We will test the robustness of the results through sensitivity analysis by excluding low quality trials, small sample trials and high bias risks.

**Language:** Without language restrictions.

**Country(ies) involved:** South Korea.

**Keywords:** CMT (congenital muscular torticollis); Herbal Medicine; External treatment; Tuina; Systematic review; Meta-analysis.

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