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Study Protocol

Effectiveness and safety of acupotomy for lumbar disc herniation: a study protocol for a randomized, assessor-blinded, controlled pilot trial

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ABSTRACT

Background: Acupotomy aims to reduce pressure on the nerve, improve surrounding blood circulation, and recover the kinetic state of soft tissue in treating lumbar disc herniation. Although several previous studies have suggested the potential use and substantial benefits of acupotomy, there is still insufficient evidence regarding this technique. This trial is designed to determine if acupotomy is more effective than manual acupuncture in improving low back pain and/or leg pain, disability, lumbar mobility, and quality of life in patients with herniated lumbar disc.

Methods: Fifty eligible patients will be randomly assigned to an acupotomy group or a manual acupuncture group in a 1:1 ratio. The experimental group will receive acupotomy at the affected side's inner core muscles and soft tissue at the level of the herniated disc where tenderness appears (twice per week for 2 weeks). The control group will receive manual acupuncture (thrice per week for 2 weeks) at GV3 (Yaoyangguan) and the bilateral BL23 (Shenshu), BL24 (Qihaishu), BL25 (Dachangshu), and BL26 (guanyuanshu) for local points and the bilateral GB30 (Huantio), BL40 (Weizhong), and BL60 (Kunlun) for distant points. The primary outcome will be the mean change in the visual analog scale from baseline to 4 weeks (2 weeks after final treatment). The Oswestry Disability Index, Modified-Modified Schober Test, and EuroQol five dimensions questionnaire will determine secondary outcomes. Adverse events will be evaluated at every visit.

Discussion: This study will provide valuable data and insights for a confirmative, full-scale randomized controlled trial to determine the clinical effects of acupotomy.

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1. Introduction

Lumbar disc herniation is one of the most common degenerative spinal disorders in young and middle-aged patients. It may cause low back pain (LBP) and/or radicular pain, paresthesia, and weakness in the lower limbs.[1,2] It is highly prevalent among patients aged 30–50 years, with 95% of herniated discs occurring at the L4/L5 and L5/S1 levels.[3] Conservative treatment is primarily sought to reduce pain by either analgesics or decreasing pressure on the affected nerve root, except in cases of surgery owing to severe sciatica, serious/progressive neurologic deficits, or persistent symptoms lasting >6 months.[4]

Acupotomy was first introduced in China in 1976 by Zhu Hanzhang. It has been used for treating chronic pain and eliminating obstinate lesions by incising the synechia and removing the attached tissue with a flat-head bladed needle.[5,6] Although it has more recently been investigated in Korea, the use of acupotomy has increased among Korean Medicine Doctors. Furthermore, an advanced acupotomy procedure with newly developed needles has been proposed.[6] According to a review of the trends in acupotomy from January 1999 to May 2014,[7] many studies have focused on musculoskeletal diseases arising in the neck and low back. In addition, four studies Q5 regarding lumbar disc herniation reported improvements in pain and disability after acupotomy. When treating lumbar disc herniation, acupotomy aims to reduce pressure on the nerve, improve surrounding blood circulation, and recover the kinetic state of soft tissue.[5,6] Although several previous studies have suggested the potential use and substantial benefits of acupotomy,[6,8–12] there is still insufficient evidence regarding this technique level owing to small sample sizes and its combination with other therapies (e.g., acupuncture, herbal medicine, physical therapy).[7]

Therefore, in this pilot randomized controlled trial (RCT), we will evaluate the effectiveness and safety of acupotomy in treating herniated lumbar disc compared with manual acupuncture for use in a future large-scale clinical trial.

2. Methods and design

2.1. Study design

This study will be an equal randomized, two parallel-armed, assessor-blinded, single center, pilot clinical trial. The flow diagram for the study is displayed in Fig. 1. Since this is a pilot study preliminary to a full-scale trial, we assume that total 25 participants in each group will be an acceptable sample size, considering 20 participants in each group with a 20% dropout rate. A total of 50 participants with symptomatic lumbar disc herniation will be recruited from the outpatients at Daejeon University Dunsan Korean Medicine Hospital (DUDKMH) through advertisements on a bulletin board, on the hospital homepage, and in local newspapers. Recruitment is expected to commence in August 2016 and end in February 2017.

At the first visit, all participants will be provided with a detailed explanation of the study protocol, written information, and an informed consent form. Study volunteers will undergo a blood test to evaluate coagulation factors and complete blood counts. As a screening process for eligibility, potential participants presumed to have lumbar disc herniation by physical examination will undergo a computed tomography (CT) scan, if an imaging test has not been performed in the last 5 years. Eligible participants who meet the study criteria will be randomly allocated to either the acupotomy treatment group or the manual acupuncture treatment group in a 1:1 ratio. Outcomes measured at the screening visit will be considered to be baseline data. The assigned intervention will start within 3 days of the screening visit. The participants will be treated for 2 weeks and asked to visit the hospital for a follow-up visit 2 weeks after the final treatment. A participant, for any reasons (e.g., unsatisfactory treatment, worsening disease), may withdraw consent on the intervention and decline to participate further by his/her own request.

2.2. Types of participants

2.2.1. Inclusion criteria

Participants who meet all the following criteria will be allowed for enrollment:

1) A confirmed diagnosis of lumbar herniated disc by CT or magnetic resonance imaging (MRI) within the past 5 years
2) At least one of the following symptoms: LBP, radiating pain in a lower extremity, and paresthesia in a lower extremity
3) Age of 20–80 years
4) Able and willing to comply with the intervention and follow-up evaluation
5) Able to provide a written informed consent

2.2.2. Exclusion criteria

Participants with any of the following conditions will be excluded:

1) History of hypersensitivity to acupuncture
2) Current affliction or history of surgery to treat cauda equina syndrome or neurological symptoms, such as motor and/or sensory paralysis
3) History of plate internal fixation or spinal fusion operatio
4) History of neuromyopathic scoliosis or neurodegenerative disease
5) Pregnancy, lactation, or a plan to become pregnant during childbearing years
6) History of neurotic or major psychiatric disability or cognitive instability
7) Terminal illness requiring active therapy
8) History of alcoholism or drug abuse
9) Hemorrhagic disease, uncontrolled diabetes, or cardiovascular disease, and/or factors that can affect hemostasis, such as anticoagulant or antiplatelet drug use
10) Disability affecting communication and concentration
11) Patients who are considered to be inappropriate for the study by the researcher

2.3. Randomization and blinding

A random allocation of the eligible participants in a 1:1 ratio will be conducted at the second visit using the block randomization method of SAS version 9.1.4 (SAS Institute, Inc., Cary,

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