Ethics Committee of Women's Hospital, School of Medicine, Zhejiang University
(English version)

Version：2.1
Version Date：2024.05.16

Informed Consent-Notification Page

Dear Participant:

We would like to invite you to participate in a clinical study entitled "Effect of acupoint hot compress on relieving pain in primiparous women during the latent phase of the first stage of labor: A study protocol for a prospective, multi-center, randomized controlled clinical trial". Before deciding whether to participate in this study, please read the following information carefully. It will help you understand the purpose, procedures, potential benefits, risks, and discomforts of the study. You may ask your doctor to explain any part of the content to help you make an informed decision.

1. Background

Pain is described as an unpleasant subjective sensation and represents one of the five vital signs. Labor pain is an unavoidable feature of childbirth and is characterized by extreme intensity. Adequate pain management is thus essential, not only for addressing physiological pain but also for mitigating the negative effects of pain on the psychological well-being of parturients.

The treatments for relieving labor pain are classified primarily into pharmacological and non-pharmacological approaches. Medication is the most frequent form of pain relief used in mainstream medical practice. However, the possible negative consequences of the drugs on both the mother and fetus have led to interest in non-pharmacological treatments to reduce labor pain during childbirth.

Acupoint hot compress, as a non-pharmacological intervention, is a non-invasive treatment based on the principles of Traditional Chinese Medicine (TCM). Many studies have shown the benefits of acupoint hot compress; notably, it is inexpensive, simple to use, safe, and effective, and can assist in reducing pain as well as preventing emotional disturbances and disorders. We thus plan to conduct a randomized controlled clinical trial to investigate the efficacy of acupoint hot compress in the reduction of labor pain in primiparous women during the latent phase.

2. Objective

This study aims to evaluate the effect of acupoint hot compress on pain relief in primiparous women during the latent phase of labor, as well as its impact on key maternal and neonatal outcomes, including labor duration, intrapartum and postpartum bleeding, maternal depression symptoms, and neonatal Apgar scores.

3. Interventions

Each participant will be assigned a random number. Based on the random number, you will be assigned to either the intervention group or the control group.The controls will be treated only with obstetrical care, while those in the intervention group will receive the same obstetrical care as the control group, with the addition of acupoint hot compress therapy at 42 ± 2 °C for four hours, starting one hour after the onset of regular uterine contractions during the latent phase of labor. For the intervention, this will be applied using a Hu-Chao-Nuan-Gong-Bao, a licensed Class II item of medical equipment (license No. 20192090292) manufactured by Jiangxi Shenghe Industrial Development Co., Ltd. (Nanchang, China).

4. Expected Number of Participants

1100

5. Inclusion criteria

The inclusion criteria are: Age ranging from 20 to 34 years; gestational age ranging from 37 to 41 weeks; primiparous parturient women with planned vaginal delivery; singleton pregnancy; meet the diagnostic criteria of the latent phase of the first stage of labor; ability to communicate well with the researcher and comply with the test requirements; and provided written informed consent.

6. Exclusion criteria

(1) Prior uterine surgery or uterine abnormalities;

(2) Fetal anomalies, chromosomal abnormalities, or stillbirth;

(3) Prenatal diseases, including infectious, central nervous system, urogenital diseases, and internal and surgery-related diseases, as well as the use of long-term medication;

(4) A history of psychiatric or neuropsychological disorders, as well as impaired

verbal communication;

(5) The presence of severe diabetes, skin diseases, sensory disorders, acute inflammation, high fever, and allergies to the material used in the study product;

(6) Patients with incomplete information.

7. Withdrawal criteria

(1) Adverse events (AEs) related to the intervention (e.g., skin burns, severe allergic reactions) occur;

(2) Participants fail to comply with the study protocol;

(3) Participants will have the option to voluntarily withdrawal at any time and for any reason.

8. Drop-out criteria

(1) Change from vaginal delivery to cesarean section;

(2) Non-completion of the intervention;

(3) The principal researcher will have the authority to conclude the study at any time when the benefits are considered to outweigh the risks;

(4) Poor treatment compliance by the subject.

9. Risks and Benefits

Risks: In previous studies, the acupoint hot compress has not shown significant adverse effects. However, there is a possibility that the intervention may not achieve the desired effect, and rare cases of allergies or burns may occur.

Prevention Measures: If you are assigned to the intervention group and experience any adverse reactions during the use of the device, you may contact the researcher at any time for guidance. The study will strictly adhere to inclusion and exclusion criteria and monitor the quality of the medical device.

Benefits: Participants will receive free acupoint hot compress devices and expert consultations, gain knowledge about labor pain relief methods, and may experience reduced pain during the latent phase. The study aims to contribute to the understanding of TCM methods for labor pain relief and improve natural delivery rates. However, individual benefits may vary.

10. Alternatives available

Although the study intervention shows promise, it is not the sole available method for labor pain relief. If you are unable to continue the study, you may inquire about alternative methods such as free position, music therapy, etc.

11. Costs and Compensation

Costs: The acupoint hot compress device will be covered by the study, with no additional costs to participants.

Compensation: None.

Compensation for Harm: Researchers will make every effort to prevent and treat adverse events that may result from this study. If any harm related to the study occurs and is confirmed, the researcher will provide diagnostic and treatment costs as well as financial compensation in accordance with relevant laws and guidelines.

12. Confidentiality Measures

Your identity will remain confidential. Your name will not appear in any study reports or publications. Medical data will be used solely for research purposes and not for commercial activities. Researchers may access your medical records, and every effort will be made to protect your privacy within legal limits. You have the right to access your information at any time during the study.

13. Voluntary participation

Your participation is completely voluntary. You may not participate or you may withdraw from the study at any time during the course of the study. This will not affect your relationship with the medical staff and your routine medical care will not be affected in any way.

14. Participant Responsibilities

(1) If you meet the inclusion criteria, you may voluntarily participate by signing the informed consent. If you choose not to participate, you will receive appropriate care based on your condition and preferences.

(2) If you participate, you will be assigned to a group and expected to cooperate with the researchers for examinations and follow-ups.

15. Contact information

If you experience any discomfort, or if you have any questions about the study,

you may contact the researcher: Name:*** Phone:**********

If you have any questions about your rights as a participants, you can contact the Ethics Committee: Phone:**********

16. Other Matters

It is up to you and/or your family to decide whether to participate in this study. Before making your decision, please ask your doctor any questions until you fully understand the study. Thank you for reviewing this information.

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Informed Consent-Signature page

Declaration of Consent

I have carefully read the above information about this study. The researcher has explained the study's characteristics and potential issues in detail and answered my questions.

I fully understand the content, risks, and benefits of participation. After sufficient time to consider, I voluntarily agree to participate and will cooperate with the researchers, providing accurate and objective information about my health and related conditions.

I understand that I may consult the doctor for further information at any time and may withdraw from the study without discrimination or retaliation, with no impact on my medical care or rights. If I fail to comply with the study plan or if study-related injuries or other issues arise, the researcher may terminate my participation.

I acknowledge that I will receive a copy of this informed consent.

Finally, I agree to participate in this study and will follow the instructions to the best of my ability.

Participant Signature:_____

Legal Guardian Signature (if applicable):_____

(Relationship to Participant:_____)

Witness (if applicable)：_____

Phone：_____

Date of signature:_____

Researcher Signature:_____

Phone：_____

Date of signature:_____