

# Effects of electrical nerve stimulation during the first stage of labor

<b>Submission date</b> 28/11/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 11/12/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/02/2021	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Labor pain during childbirth is inevitable and can negatively affect labor and the mother and baby's progress. Pain relief during labor is essential to reduce its physiological consequences. Transcutaneous electrical nerve stimulation (TENS) was introduced in obstetrics in 1970. TENS is a treatment that administers mild electrical currents to the skin to relieve pain. TENS' effectiveness at reducing labor pain is still debatable among obstetricians. Therefore, this study aims to evaluate TENS therapy's effects on labor pain intensity and the duration of the active phase of labor.

### Who can participate?

Pregnant women aged 18 and over who attend the Hunan Provincial People's Hospital (The First Affiliated Hospital of Hunan Normal University) Changsha, Hunan province (China) obstetrics department between March 2017 and June 2017

### What does the study involve?

Participants are randomly allocated to the experimental group (to receive TENS therapy in the first stage of labor) or the control group (to receive routine obstetric care). The researchers and midwives collect labor pain scores at the start of the study, 30, 60, 120 minutes after TENS therapy, and 2-24 hours after delivery. After birth, they collected obstetrics and infant outcomes data. Obstetrics data include oxytocin usage, duration of first, second, and third stages of labor, postpartum blood loss, and adverse events. At the same time, infant data is collected including Apgar scores and baby weight.

### What are the possible benefits and risks of participating?

Women will be taking an active role in managing labor pain during delivery. The risk of participating in this study is minimal. Researchers stated skin redness at the electrode sites as the only possible side effect, and these symptoms usually disappear spontaneously within a few days. The principal researcher obtains the women's informed consent after explaining the purpose, function, potential advantages, and risks associated with the study. Women are permitted to withdraw from the course at any point in time without affecting their obstetric care. The researchers use no names or easily identification material. The researchers keep the participant's information confidential.

Where is the study run from?  
Hunan Provincial People's Hospital (The First Affiliated Hospital of Hunan Normal University)  
(China)

When is the study starting, and how long is it expected to run for?  
March 2017 to June 2017

Who is funding the study?  
Central South University (China)

Who is the primary contact?  
Prof. Yang Luo  
ly603202@csu.edu.cn

## Contact information

### Type(s)

Public

### Contact name

Prof Yang Luo

### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

201421200008

## Study information

### Scientific Title

The effects of transcutaneous electrical nerve stimulation during the first stage of labor: a randomized controlled trial

### Study objectives

1. There will be differences in labor pain scores at 30, 60, and 120 minutes after using TENS therapy among the intervention group compared to their counterparts in the control group.
2. There will be differences in time spent during the active phase of labor among TENS users than compared to the control group.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 10/12/2016, Hunan Provincial People's Hospital (The First Affiliated Hospital of Hunan Normal University) ethics committee (61 Jiefang West Road, Furong Changsha, Hunan, 410005, China; + 86 (0)731 84913336; no email provided), ref: S1703567

### **Study design**

Single-center single-blind randomized controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Labor pain among pregnant women during the first stage of labor

### **Interventions**

A researcher (blinded for the group) randomly assigns participants (at a 1:1 ratio) to the experimental group (received TENS therapy in the first stage of labor) or the control group (receives routine obstetric care) using a simple technique based on a computer-generated list.

A midwife and a researcher initiate TENS therapy at the beginning of active labor (4-cm cervical dilatation) until the second labor stage. The researcher records the pain scores immediately after the randomization, at 30, 60, and 120 minutes after TENS therapy and 2-24 hours post-delivery. The intervention uses the following procedures: a midwife and a researcher enter participants' demographic and obstetrics information into a TENS unit system before the intervention; the midwife applies two pairs of electrodes on both arms at hegu points (LI4, the midpoint between first and second carpal bones, first web space dorsal side) and neiguan points (PC6, 4 cm above the medial transverse line in wrist); the midwife places two electrodes over the participants' paravertebral regions at the T10–L1 and S2–S4 levels; two transducers (probes) are placed on the abdomen to monitor fetal heart rate and uterine contractions; finally, the midwife activates the labor analgesia icon. This study uses an SRL998A Bio-feed TENS System (Sunray Medical Apparatus CO. LTD. Guangzhou, China). It produces a peak current of 15 mA and a peak open-circuit voltage of 300 V. According to the woman's maximum tolerance, the midwife adjusts the frequency and intensity of analgesia, characterized by a buzzing or pricking sensation without muscle contraction.

All pregnant women receive standard obstetric care according to Chinese clinical practice guidelines. This care includes continuous fetal heart monitoring, administration of oxygen 2 liters per minute, vaginal examinations, and oxytocin administration if necessary.

### **Intervention Type**

Device

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

SRL998A Bio-feed Tens System TENS Unit (Sunray Medical Apparatus CO.LTD. Guangzhou, China)

**Primary outcome(s)**

Labor pain measured using a visual analog scale (VAS) chart immediately after the randomization (baseline), 30, 60, and 120 minutes after TENS therapy

**Key secondary outcome(s)**

Obstetric outcome measures:

1. Cervical dilatation assessed by four-hourly vaginal examinations
2. Usage of oxytocin calculated by the number of doses administered during delivery
3. Duration of the first active labor stage calculated using a digital wall clock from 4 to 10-cm cervical dilation
4. The second stage of labor calculated using a digital wall clock from 10-cm cervical dilation to the fetus's delivery
5. The third stage of labor calculated using a digital wall clock from the fetus's delivery to delivery of the placenta
6. Postpartum hemorrhage measured by quantifying all the blood lost during the second and third stages
7. Pain 2-24 hours post-delivery assessed using VAS chart 2 hours after delivery but within 24 hours after delivery
8. Any adverse event assessed using four-hourly vital signs (blood pressure, pulse, respiration, and temperature) before, during, and 24 hours after delivery

Neonatal outcome measures:

1. Apgar scores performed using the Apgar scores chart immediately after the baby was born and at 5 and 10 minutes
2. Baby weight measured using a weigh scale after birth

**Completion date**

30/06/2017

**Eligibility**

**Key inclusion criteria**

1. Pregnant women volunteers aged 18 years and above
2. At term (37-42 weeks gestation age)
3. Primipara and multipara with no complications during the antenatal period
4. Established an active stage of labor
5. A single viable fetus in cephalic presentation

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

Female

**Total final enrolment**

326

**Key exclusion criteria**

1. Preterm labor
2. Malpresentation
3. Cephalopelvic disproportion
4. Precipitated labor
5. Previous history of cesarean section
6. Antepartum hemorrhage
7. Any medical complications
8. Known fetal abnormalities
9. Multiple gestations
10. Women in the advanced stage of labor
11. Psychiatric disorders
12. Previous history of using TENS
13. Skin lesions on the electrodes' application sites

**Date of first enrolment**

08/03/2017

**Date of final enrolment**

28/06/2017

**Locations**

**Countries of recruitment**

China

**Study participating centre**

**Hunan Provincial People's Hospital (The First Affiliated Hospital of Hunan Normal University)**

61 Jiefang West Road

Changsha

China

410005

# Sponsor information

## Organisation

Central South University

## ROR

<https://ror.org/00f1zfq44>

## Funder(s)

### Funder type

University/education

### Funder Name

Central South University

### Alternative Name(s)

Central South University in Hunan, , CSU

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Universities (academic only)

### Location

China

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Yang Luo (ly603202@csu.edu.cn), Lizhen Hu (Joyhu1964@126.com), and Anne Njogu (annienyambura2012@yahoo.com) after the trial article is published. Informed consent on data sharing was obtained from all participants involved in the study. For each dataset request, a data-sharing form will be completed describing the purpose and scope of use of the data. This form will have to go through the Hunan Provincial People's Hospital (The First Affiliated Hospital of Hunan Normal University) ethics committee for approval. The datasets are held on a secure server at the Hunan Provincial People's Hospital in anonymized form. This data will be stored at this site for ten years following the regulations of the Hunan Normal University.

### IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	24/02/2021	26/02/2021	Yes	No