ISRCTN23857995 https://doi.org/10.1186/ISRCTN23857995

Effects of electrical nerve stimulation during the first stage of labor

Submission date
28/11/2020

Recruitment status
No longer recruiting

Registration date
11/12/2020

Overall study status
Completed

Last Edited
26/02/2021

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
Xiangya School of Nursing
Central South University
Changsha
China
410013
+86 (0)73182650270
ly603202@csu.edu.cn

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Secondary outcome measures
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

Overall study start date
01/03/2017

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
The researchers based the sample size calculation on the primary outcome (pain intensity) and a previous study's statistical indices. The researchers assumed the mean difference of the VAS score between both groups was 1.2, and the standard deviation was 3. The ratio of the experimental group size to the control group size was 1:1. Therefore, the study required 286 women to detect the actual difference with a power of 90% and alpha of 0.05 (two-sided).

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

Sponsor details
Xiangya School of Nursing
Changsha
China
410013
+86 (0)731 82650270
ly603202@csu.edu.cn

Sponsor type
University/education

Website
http://iecd.csu.edu.cn/en-US/

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

Publication and dissemination plan
The researchers have submitted a manuscript for publication in a high-impact peer-reviewed journal

Intention to publish date
25/12/2020

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?
Results article	results	24/02/2021	26/02/2021	Yes	No