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Transcranial magnetic stimulation reduces pain and analgetic use in breast cancer patients

Submission date
28/01/2023

Recruitment status
No longer recruiting

Registration date
17/03/2023

Overall study status
Completed

Last Edited
15/03/2023

Condition category
Signs and Symptoms

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Cancer patients commonly experience pain. Advanced breast cancer patients experience pain due to the involvement of other structures, as well as due to the cancer treatment. Transcranial magnetic stimulation (TMS) is a new non-invasive brain stimulation method for pain management. This treatment has been proven to decrease pain and increase beta-endorphin levels in other chronic pain patients. This research aimed to study the effect of TMS on pain intensity, opioid usage, and serum beta-endorphin levels in breast cancer patients.

Who can participate?
Inpatient and outpatient breast cancer patients, 19–60 years old

What does the study involve?
The P1 group receive TMS for 20 minutes. Five sessions of TMS are administered, with one session per day, by a researcher or assistant. The P2 group was the control group and received no TMS. All patients in both groups continued analgesic treatment according to their therapeutic dose.

What are the possible benefits and risks of participating?
The use of TMS for pain therapy has been widely carried out and has a satisfactory effect, especially in patients with chronic pain (pain for over 3 months) who do not improve with drug therapy even with high doses of opioids, which can cause unpleasant side effects. The use of TMS is expected to reduce pain so that the amount of drugs consumed also decreases. TMS is non-invasive so that the patient is more comfortable, and the dose can be adjusted, thus minimizing the side effects of TMS. Side effects that can occur include headache/neck pain (non-steroidal anti-pain drugs can be given). If hearing loss occurs the volume of the device can be reduced and the patient can be given earplugs during therapy. If the patient feels anxious and uncomfortable the SMT intervention is stopped and the patient is calmed and if a seizure occurs the SMT intervention is stopped and the patient is treated as a seizure patient. In this study, the usual dose was used for pain therapy. In addition, tools and medicines are prepared for handling emergency conditions according to standard procedures.

Where is the study run from?
Hasanuddin University Hospital, Makassar (Indonesia)

When is the study starting and how long is it expected to run for?
April 2022 to August 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Nur Surya Wirawan, acoanestesi@yahoo.com

Contact information

Type(s)
Principal investigator

Contact name
Dr Nur Surya Wirawan

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Additional identifiers

Protocol serial number
UH22030114

Study information

Scientific Title
The effect of transcranial magnetic stimulation on pain intensity and opioid use in breast cancer patients and on serum beta-endorphin levels: a randomized controlled trial

Acronym
TETMSPIOUBCPSBEL:RCT

Study objectives
Transcranial magnetic stimulation (TMS) reduces pain intensity and opioid usage and increases serum beta-endorphin levels in breast cancer patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/04/2022, Ethical Committee of Human Biomedical Research of the Hasanuddin University Faculty of Medicine (Jl. Perintis Kemerdekaan Kampus, Tamalanrea Km.10, Makassar, Indonesia; +62 (0)411 5044671; agussalim.bukhari@yahoo.com), ref: 172. 1UN4.6.4.5.3U PP36 /2022 and protocol UH22030114

Study design
Prospective randomized controlled trial with a pre-test–post-test design

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pain in breast cancer patients

Interventions
The P1 group received 10-Hz transcranial magnetic stimulation for 20 minutes, at 80% of the motor threshold, with 100 pulses/train to 20 pulses/session, and with a 50-second intertrain interval. A figure-of-8 coil was used to deliver stimulation at M1. Five sessions of transcranial magnetic stimulation were administered, with one session per day, by a researcher or assistant. The P2 group was the control group (receives no TMS). All patients in both groups continued analgesic treatment according to their therapeutic dose.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Measured at baseline and after five sessions:
1. Pain intensity measured using a numerical rating scale (NRS) from 0-10
2. Opioid usage recorded using medical records
3. Serum beta-endorphin level measured using enzyme-linked immunosorbent assay (ELISA) kit for beta-endorphin

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
01/08/2022

Eligibility

Key inclusion criteria

1. 19–60 years old
2. Used analgesics combined with opioids for pain
3. Agreed to enrol in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
40

Key exclusion criteria
1. Current chemotherapy treatment containing alkaloids vinca, taxane, platinum-based preparations
2. Electrodes implanted inside the head
3. Cochlear implants
4. History of head trauma, seizure, or syncope
5. Brain lesions
6. On drug withdrawal
7. Pregnant during the study period
8. Patient left the study
9. Insufficient blood samples for evaluating serum beta-endorphins obtained

Date of first enrolment
13/04/2022

Date of final enrolment
01/06/2022

Locations

Countries of recruitment
Indonesia

Study participating centre
Hasanuddin University Hospital
Jl. Perintis Kemerdekaan No.KM 10
Tamalanrea Indah
Kec. Tamalanrea
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Indonesia
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Sponsor information

Organisation
Hasanuddin University

ROR
https://ror.org/00da1gf19

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Nur Surya Wirawan (acoanestesi@yahoo.com).

IPD sharing plan summary
Available on request