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Does electrostimulation reduce the demand for analgesics after surgery?

Submission date	**Recruitment status**	[X] Prospectively registered
07/12/2020	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
13/01/2021	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
13/01/2021	Surgery	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Pain after surgery is one of the biggest concerns of both patients and surgeons. Despite many publications, consensuses, and guidelines, the clinical reality is far from perfect. It is reported that up to 50% of patients claim that after surgery the pain relief was insufficient. The aim of this study is to assess the effectiveness and safety of transcutaneous electrical acupoint stimulation (TEAS) for the treatment of patients after thyroidectomy (removal of the thyroid gland) compared with a sham treatment group and a no-treatment group.

Who can participate?
Patients aged 18–75 undergoing elective thyroidectomy

What does the study involve?
Participants are randomly allocated to one of three groups. The intervention group receives complementary TEAS in addition to drug treatment (morphine through a patient-controlled analgesia [PCA] device). The electrostimulation begins immediately after surgery. The TEAS group will receive stimulation for 30 minutes at intervals of 2 hours. The treatment will automatically stop at the end of each 30-minute treatment interval. The sham group will be equipped with fake devices, which appear exactly like TEAS with the "in use" light flashing regularly. The participants will be forewarned that they may not sense the electrical stimulation. The control group receives only PCA treatment after surgery. Patients will be asked a series of questions about their quality of life at the start and end of the study. Both PCA and TEAS/sham treatment will be stopped 24 hours after the surgery.

What are the possible benefits and risks?
Participants may benefit from receiving non-invasive and relatively safe treatment. The risks and side effects that may arise during the study are mild discomfort at the stimulator's location or rash-like skin irritation.

Where is the study run from?
Wroclaw University Hospital (Poland)

When is the study starting and how long is it run for?
September 2017 to March 2022

Who is funding the study?
Ministry of Science and Higher Education (Poland)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
0105/DIA/2017/46

Study information

Scientific Title
Analgesic effect of transcutaneous electrical acupoint stimulation in patients undergoing thyroidectomy

Acronym
TEASTh

Study objectives
1. Transcutaneous electrical acupoint stimulation is more effective at reducing postoperative opioid consumption in patients undergoing thyroidectomy, compared to standard and sham treatment.
2. Transcutaneous electrical acupoint stimulation is effective at decreasing pain intensity in patients undergoing thyroidectomy, compared to standard and sham treatment.
3. Transcutaneous electrical acupoint stimulation is effective at decreasing the frequency of complications in patients undergoing thyroidectomy, compared to standard and sham treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/09/2017, Bioethics Committee - Wroclaw Medical University (50-367 Wrocław, Pasteura 1 St., Poland; +48 (0)71 784 10 14, 71 784 17 10; bioetyka@umed.wroc.pl), ref: KB 599 /2017

Study design
Single-center single-blinded placebo-controlled interventional 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 the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Pain and opioid consumption after surgery

Interventions
Enrolled participants will be randomly assigned to TEAS, sham, or a control group (1:1:1). An independent, blinded statistician will generate the block randomization scheme. The table will be managed by an independent researcher who is not involved in the recruitment, treatment, or assessment. The participants will be blinded to the type of treatment.

Upon arrival to the postoperative care unit, the patient will be equipped with a Patient Controlled Analgesia (PCA) device, programmed to deliver 1 mg bolus doses of morphine "on-demand" i.v. with a minimal lockout interval of 10 min and a maximum 4 h dose of 15 mg on the authority of standardized hospital protocol. PCA therapy will be initiated in the postanesthesia care unit as soon as the patient will be sufficiently alert to wield the controller, as the principles of the therapy will be explained before the surgery. If the patient requires pain medication prior

to starting PCA therapy, an incremental dose of metamizole 1 g intravenously, will be administered by the postoperative care unit nursing staff. Alongside PCA, analgesic therapy will be supplemented with TEAS/sham therapy, which will begin when the patient arrives at the postoperative care unit.

Stimulation will be carried out using four wireless small electro-stimulators (StimulAid Inc, Poland). A point-detection function in the device will confirm the correct localization of the stimulator. The TEAS group will receive mixed frequency stimulation (alternating at 2 and 100 Hz every 3 s) in continuous mode for 30 min at intervals of 2 h. The device will automatically shut off at the end of each 30 min treatment interval. The strength of the stimulation will be adjusted to each patient to achieve a modest tremor of the regional muscle and maintain De-Qi sensations, such as numbness and tingling. In both groups, electro-stimulators will be applied bilaterally to LI4 (He Gu) and P6 (Neiguan) points. The sham group will be equipped with fake devices, which look exactly like TEAS with the "in use" light flashing regularly; nevertheless, the patients will be told that they may not be able to feel the stimulation. The patients in TEAS and sham groups will be notified that they are receiving electrical stimulation.

The control group receives only PCA treatment postoperatively.

Patients will be asked a series of questions about their quality of life at the start and end of the study. Both PCA therapy and TEAS/sham will be ceased 24 hours after the surgery.

Intervention Type
Mixed

Primary outcome measure
Total morphine dose (TMD) received by patient measured in mg while using PCA device in the 24 hours after surgery

Secondary outcome measures
1. The number of PCA demands, measured by times the button is pressed by the patients in the postoperative period
2. Pain measured using the score on the Visual Analogue Scale before surgery and at 4, 8, 12, 16, and 20 hours post-operation
3. The occurrence of opioid-related side effects recorded by the medical staff during the first 24 hours post-surgery

Overall study start date
01/09/2017

Completion date
01/03/2022

Eligibility

Key inclusion criteria
1. Male and female patients aged 18–75 years
2. Patients undergoing elective thyroidectomy, Bethesda II-IV in thyroid BAC
3. Body mass index 18–30 kg/m²
4. ASA classification I–III
5. Patients able to provide an informed, signed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Patients with Bethesda V and VI in thyroid BAC
2. Patients with recurrent goiters
3. Patients with a history of allergy, hypersensitivity, or addiction to opioids
4. History of opioid intake in the past month
5. Use of monoamine oxidase and selective serotonin reuptake inhibitors
6. Patients with implanted pacemakers or cardioverter-defibrillator
7. Patients with a history of significant cardiovascular, pulmonary, renal, hepatic, or neurological disease
8. Patients with skin lesions, incision, or scar at the LI4 or P6 acupoint
9. Patients who participated in other clinical trials or received other acupuncture therapy in the previous 4 weeks

Date of first enrolment
01/02/2021

Date of final enrolment
01/02/2022

Locations

Countries of recruitment
Poland

Study participating centre
Univeristy Hospital in Wroclaw
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Sponsor information

Organisation
Ministry of Science and Higher Education

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Sponsor type
Government

Website
https://www.gov.pl/web/science

Funder(s)

Funder type
Government

Funder Name
Ministerstwo Nauki i Szkolnictwa Wyższego

Alternative Name(s)
Ministerstwo Nauki i Szkolnictwa Wyższego, Ministry of Science and Higher Education, Ministry of Science and Higher Education, Republic of Poland, MNiSW

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Poland

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal. The protocol will be available online soon.

Intention to publish date
01/04/2022

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary
Other