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Can electrostimulation reduce the requirement for opioids in patients after surgery?

Submission date	**Recruitment status**	[_] Prospectively registered
05/10/2020	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/10/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/12/2022	Surgery	

Plain English summary of protocol

Background and study aims
Patients perceive postoperative pain as one of the most unpleasant aspects of undergoing surgery. Despite numerous arguments supporting the need for effective treatment of postoperative pain, the clinical reality is still far from satisfactory. It is reported that nearly half of all surgical patients suffer from persistent postsurgical pain. The aim of this study is to evaluate the efficacy and safety of transcutaneous electrical acupoint stimulation (TEAS) in the postoperative treatment of patients undergoing inguinal hernia repair compared with a sham treatment group and a no treatment group.

Who can participate?
Adults undergoing elective laparoscopic mesh inguinal hernia repair

What does the study involve?
The intervention group receives adjuvant TEAS in addition to pharmacological therapy (morphine through a patient-controlled analgesia [PCA] device). Participants receive stimulation after completion of the surgical procedure. The TEAS group will receive stimulation for 30 minutes at intervals of 2 hours. The device will automatically shut off at the end of each 30-minute treatment interval. The sham group will be provided with the same devices as TEAS with the "in use" light flashing in the usual manner, but the participants will be told that they may not be able to feel the electrical stimulation. The control group receives the same procedure, with the difference of instead of TEAS, the participants receive only PCA treatment. Patients will be interviewed about their condition at the start and end of the study. The PCA therapy and TEAS /sham will be discontinued at 24 hours after the surgery.

What are the possible benefits and risks?
Participants who are enrolled in the study may benefit from receiving relatively safe treatment which is believed to be cost-effective. The risks and side effects that may arise during the study are local skin infection, mild pain or 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 December 2020

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

Who is the main contact?
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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
KB 599/2017

Study information

Scientific Title
Transcutaneous electrical acupoint stimulation to reduce opioid consumption in patients undergoing inguinal hernia repair

Acronym
TEASIIHR

Study objectives
1. Transcutaneous electrical acupoint stimulation is more effective at reducing postoperative opioid consumption in patients undergoing inguinal hernia repair, compared to standard and sham treatment.
2. Transcutaneous electrical acupoint stimulation is effective at decreasing pain intensity in patients undergoing inguinal hernia repair, compared to standard and sham treatment.
3. Transcutaneous electrical acupoint stimulation is effective at decreasing the frequency of complications in patients undergoing inguinal hernia repair, 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 interventional single-blinded placebo-controlled 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
Postoperative pain in patients undergoing inguinal hernia repair

Interventions
Enrolled participants will be randomly assigned to TEAS, sham, or 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.

On a patient's arrival in the postanesthesia care unit, the PCA device will be connected to the patient's intravenous line and programmed to deliver 1 ml bolus doses of morphine (1 mg) "on-demand," with a minimal lockout interval of 10 min and a maximum 4 h dose of 15 mg according to a standardized hospital protocol. PCA therapy will be initiated in the postanesthesia care unit when the patient was sufficiently alert to understand and operate the PCA device. If the patient

requires pain medication prior to starting PCA therapy, an incremental dose of metamizole 1 g intravenously, will be administered by the postanesthesia care unit nursing staff. The postoperative PCA analgesic therapy will be supplemented with TEAS/sham therapy, which will start when the patient arrives in the postanesthesia care unit.

Stimulation will be performed using four portable coin-sized 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 intensity of the stimulation will be adjusted to each individual to maintain a slight twitching of the regional muscle and achieve De-Qi sensations, such as soreness, distention, and heaviness. In both groups, electro-stimulators will be applied bilaterally to LI4 (He Gu) and ipsilateral to hernia to two ashi points located within a diameter of 5 cm from the incision site. The sham group will be provided with the same devices as TEAS with the "in use" light flashing in the usual manner; however, the participants will be told that they may not be able to feel the electrical stimulation. The patients in TEAS and sham groups will be told that they are receiving current stimulation. The PCA therapy and TEAS/sham will be discontinued at 24 hours.

Intervention Type
Mixed

Primary outcome measure
Total morphine dose received in mg measured using patient-controlled analgesia (PCA) device in the postoperative period

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 score on the Visual Analogue Scale prior to surgery and at 4, 8, 12, 16, and 20 hours after surgery
3. The frequency of opioid-related side effects recorded by the medical staff during the postoperative observation period

Overall study start date
05/09/2017

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. Male and female patients aged 18–75 years
2. Patients undergoing elective laparoscopic mesh inguinal hernia repair
3. Body mass index 18–30 kg/m^2
4. ASA classification I–III
5. Patients provide signed informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
90

Total final enrolment
75

Key exclusion criteria
1. Patients with bilateral or recurrent inguinal hernia
2. Patients with a history of intolerance, hypersensitivity or abuse of opioids
3. Use of opioids in the past month
4. Use of monoamine oxidase and selective serotonin reuptake inhibitors
5. Patients wearing a cardiac pacemaker
6. Patients with clinically significant cardiovascular, pulmonary, renal, hepatic and neurological disease
7. Patients with skin infections, surgical incision or scar at the point of application of acupuncture
8. Patients who participated in other clinical trials, or received other acupuncture therapy, in the previous 4 weeks

Date of first enrolment
01/01/2019

Date of final enrolment
30/11/2020

Locations

Countries of recruitment
Germany

Poland

Study participating centre
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Sponsor information

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Ministry of Science and Higher Education

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Sponsor type
Government

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

ROR
https://ror.org/05dwvd537

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
01/01/2021

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/01/2021	07/07/2021	Yes	No
Protocol article		29/12/2022	30/12/2022	Yes	No