Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Determining the effect of low-power laser therapy on midline laparotomy pain compared to placebo in upper and lower gastrointestinal surgeries

Protocol summary

Study aim

Our aim of this study is to evaluate the effect of low-power laser therapy as a complementary treatment to reduce midline laparotomy wound pain.

Design

This clinical trial with parallel control and intervention group, double-blind, randomized groups, after obtaining written consent on 100 patients who are candidates for midline laparotomy for elective surgery ; will start. The online software www.randomizer.org was used for randomization.

Settings and conduct

Laser irradiation will be done for each patient of intervention group for 6 minutes during the first three days after the operation. first dose of radiation will be done after recovery and in the ward, and the next doses will be done at intervals of 24 hours until the third day after the operation in It will be done in hospitalization at Tehran Baqiyatallah hospital. same number of sessions for the control group will also be done with a turned off device.

Participants/Inclusion and exclusion criteria

In this study,100 patients (ASA I-II) with the age range of 30 to 60 years who are candidates for midline laparotomy for elective surgery of the upper and lower gastrointestinal tract were included in the study, and by lack of satisfaction, they will be excluded from the study.

Intervention groups

The first group (control) receives the usual treatments after the operation, including intravenous and oral painkillers in case of pain, in addition to being treated with an OFF low-level laser, and the second group (study) in addition to receiving the treatments of the group First, they are treated with an ON low-level laser.

Main outcome variables

The main outcome variables of this study are evaluation the amount of pain at the midline laparotomy surgery site, the amount of serum inflammatory factors, the amount of local wound complications, in addition to assessment the amount of pain-reducing drugs in both intervention and control groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221018056225N1**
Registration date: **2022-11-27, 1401/09/06**
Registration timing: **registered_while_recruiting**

Last update: **2022-11-27, 1401/09/06**
Update count: **0**

Registration date

2022-11-27, 1401/09/06

Registrant information

Name

hamed gholizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-22, 1401/07/30

Expected recruitment end date

2023-03-19, 1401/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Determining the effect of low-power laser therapy on midline laparotomy pain compared to placebo in upper and lower gastrointestinal surgeries

Public title
Efficacy of Low Level Laser Therapy on The Post Midline laparotomy Wound Pain

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients who are in the age range of 30 to 60 years.
Patients who underwent midline laparotomy were selected for elective upper and lower gastrointestinal surgery.

Exclusion criteria:
Patients who do not agree to participate in the study.
Patients who, in addition to surgery, have other serious medical problems (ASA III-VI) or suffer from psychotic disorders or drug addiction.

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
By Using the online software www.randomizer.org, the patients were divided into two groups of 50 people, control and intervention, in a simple and individual way. Considering that the study is double-blind; The patient and the attending physician as pain evaluators will not know whether the patients belong to the control or intervention groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants and pain evaluators, as well as the researcher of this study, by considering that the randomization of patients is done by the intervention provider, are not aware of which patient received the intervention and which patient received the placebo.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Baqiyatallah Hospital

Street address
Baqiyatallah University of Medical Sciences, Baqiyatallah hospital, Department of General Surgery, Azam Ave, South Sheikh Bahai St, Molla Sadra Blvd, Vanak Square, Tehran

City
Tehran

Province
Tehran

Postal code
1435915371

Approval date
2022-06-24, 1401/04/03

Ethics committee reference number
IR.BMSU.BAQ.REC.1401.029

Health conditions studied

1

Description of health condition studied
Patients who have been admitted to the Baqiyatallah educational and therapeutic center and have undergone midline laparotomy for elective upper and lower gastrointestinal surgery will be studied.

ICD-10 code
K42

ICD-10 code description
Umbilical hernia

2

Description of health condition studied
Patients who have been admitted to the Baqiyatallah educational and therapeutic center and have undergone midline laparotomy for elective upper and lower gastrointestinal surgery will be studied.

ICD-10 code
K43

ICD-10 code description
Ventral hernia

3

Description of health condition studied
Patients who have been admitted to the Baqiyatallah educational and therapeutic center and have undergone midline laparotomy for elective upper and lower gastrointestinal surgery will be studied.

ICD-10 code
K46

ICD-10 code description

Unspecified abdominal hernia

4

Description of health condition studied
Patients who have been admitted to the Baqiyatallah educational and therapeutic center and have undergone midline laparotomy for elective upper and lower gastrointestinal surgery will be studied.
ICD-10 code
K31
ICD-10 code description
Other diseases of stomach and duodenum

5

Description of health condition studied
Patients who have been admitted to the Baqiyatallah educational and therapeutic center and have undergone midline laparotomy for elective upper and lower gastrointestinal surgery will be studied.
ICD-10 code
K25
ICD-10 code description
Gastric ulcer

Primary outcomes

1

Description
Midline laparotomy surgery site pain
Timepoint
Before beginning of the intervention, 24, 48, 72 hour's after beginning of the intervention
Method of measurement
visual analogue scale

2

Description
Local complications of the laparotomy site
Timepoint
Before beginning of the intervention, 24, 48, 72 hour's after beginning of the intervention
Method of measurement
Inspection of the operation site

3

Description
serum Inflammatory factors
Timepoint
Before beginning of the intervention, 24, 48, 72 hour's after beginning of the intervention
Method of measurement
Taking daily blood tests

Secondary outcomes

1

Description
The amount of painkillers
Timepoint
Before beginning of the intervention, 24, 48, 72 hour's after the start of the intervention
Method of measurement
check the patient's medical record

Intervention groups

1

Description
Intervention group: In addition to receiving the treatments of the first group, the intervention group is also treated with low-power laser. The distance of 2 cm from the wound after removing the surgical dressing will be 0.5 J/cm2 radiation dose. Considering that the radiation cross-section was considered to be 30 square centimeters; According to the formula t = (D. A) / P, the radiation time was calculated for 6 minutes each time. In total, the laser radiation will be done during the first three days after the operation for each patient, and its sequence will be such that the first dose of radiation It will be done after recovery and in the ward, and the next doses will be done at 24-hour intervals until the third day after the operation while in the hospital.
Category
Treatment - Devices

2

Description
Control group: The first group (control) after the operation receive the usual treatments, including intravenous and oral pain relievers in case of pain, in addition to being treated with a low-power silent laser (Placebo). In total, during the first three days after After the operation, each patient will be treated with placebo three times, and the sequence will be such that the first time will be done after recovery and in the ward, and the next times will be done at intervals of 24 hours until the third day after the operation while in the hospital. will be done.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatallah Hospital
Full name of responsible person
Hosein Samadinia
Street address
Baqiyatallah University of Medical Sciences, Baqiatallah hospital, Department of General Surgery, Azam Ave, South Sheikh Bahai St, Mollasadra Blvd,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bagheiat-allah University of Medical Sciences

Full name of responsible person
Abbas Ali Imanifooladi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Bagheiat-allah University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Bagheiat-allah University of Medical Sciences

Full name of responsible person
Mohammad Madadi Emamchai

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
General Surgery

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Position
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Latest degree
Medical doctor

Other areas of specialty/work
General Surgery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data of this study according to the plan and after the completion of the data analysis so that the patients under study are not identifiable can be received by contacting the person in charge of scientific accountability in case of decision to publish the article in the ICMJE-related journals.
When the data will become available and for how long
The access period starts 6 months after the publication of the article in ICMJE-related journals.
To whom data/document is available
All researchers of university institutes who have published articles in ICMJE-related journals will be able to access the information of this study.
Under which criteria data/document could be used
The data and analysis results of this study can only be used for inclusion in review studies.
From where data/document is obtainable
To receive the data or the results of the analysis of this study, please refer to the person responsible for the scientific response of this study, Mr. Dr. Mohammad Madadi Imamchai, with the following contact information. Address:Baqiyatallah University of Medical Sciences, Department of General Surgery, Azam Ave, South Sheikh Bahai St, Molla Sadra Blvd, Vanak Square, Tehran. Mobile number: 00989104009204 Workplace phone number: 00982181267609 Fax number: 00982188033539 Email: geniusman68@yahoo.com Postal code: 1435915371
What processes are involved for a request to access data/document
The request of receive information can be processed in a period of less than one week after checking the mentioned necessary conditions.
Comments