# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## Evaluating the efficacy of laparoscopic Transversus Abdominis Block on pain and side-effects reduction in laparoscopic bariatric surgeries in Imam Khomeini hospital complex in 2020-2021

## Protocol summary

**Study aim**

Determining the effect of laparoscopic transversus abdominis block in reducing pain and side-effects in patients undergoing laparoscopic surgery for obesity

**Design**

The study design will include a control group, with a parallel group of transversus abdominis block, three-sided blind, randomized on 36 patients. At first, patients undergoing laparoscopic obesity surgery will randomly be divided into two groups. Random assignment will be by Block randomization method, in which 5 pieces of paper with T and 5 with C written in them are placed in a bag and mixed, and then one piece of paper for each patient admitted to the study. According to what is written on the patient's paper, the patient will go to one of the two groups and for the next 10 patients, the papers will be returned to the bag and the procedure will be repeated. A similar anesthesia and analgesic method will be used in both groups.

**Settings and conduct**

This study will be performed during the years of 2020-2021 in Imam Khomeini Hospital Complex, Valiasr Hospital affiliated to Tehran University of Medical Sciences. Patients will not know which group they are in. The person in charge of collecting information and analyzing them will not know which group had the anesthetic injection and will only have the group title in English letters. This randomized clinical trial study will be performed on patients undergoing laparoscopic surgery. At first, the study conditions will be fully explained to all patients and their written consent was obtained and then they entered the study.

**Participants/Inclusion and exclusion criteria**

Candidate patients for laparoscopic obesity surgery

**Intervention groups**

laparoscopic transversus abdominis block

**Main outcome variables**

analgesics dose hospitalization length pain score

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20201007048962N1**
Registration date: **2020-12-17, 1399/09/27**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-17, 1399/09/27**
Update count: **0**

**Registration date**

2020-12-17, 1399/09/27

**Registrant information**

**Name**

Mohammad Hadi Bahri

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 21 6612 6442

**Email address**

m.bahri@abzums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2020-11-21, 1399/09/01

**Expected recruitment end date**

2021-03-19, 1399/12/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**
empty

**Scientific title**
Evaluating the efficacy of laparoscopic Transversus Abdominis Block on pain and side-effects reduction in laparoscopic bariatric surgeries in Imam Khomeini hospital complex in 2020-2021

**Public title**
The efficacy of laparoscopic Transversus Abdominis Block on pain and side-effects reduction of surgery
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Laparoscopic bariatric surgery
**Exclusion criteria:**
No patients consent for participation in the study
Patients whose surgery becomes open or an unusual complication occurs.
**Age**
No age limit
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **36**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
At first, patients undergoing laparoscopic obesity surgery will randomly divided into two groups. Random assignment will be by Block randomization method, in which 5 pieces of paper with T and 5 with C written on them are placed in a bag and mixed, and then one piece of paper will be allocated for each patient admitted to the study. According to what is written on the paper, the patient goes to one of the two groups and for the next 10 patients, the papers are returned to the bag and the process is repeated.
**Blinding (investigator's opinion)**
Triple blinded
**Blinding description**
In the intervention group, a syringe containing anesthetic will be injected. In the control group, a syringe containing normal saline and free of any anesthetic will be provided to the surgeon. So that the surgeon will not know which syringe contains the anesthetic. Injections will be given to all patients. Patients will not know which group they are in. The person collecting the information and analyzing it will not know which group had the anesthetic injection and will only have the group title in English letters.

**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Tehran University of Medical Sciences
**Street address**
Imam khomeini hospital complex, Tehran, Iran
**City**
Tehran
**Province**
Tehran
**Postal code**
1419733141
**Approval date**
2017-11-04, 1396/08/13
**Ethics committee reference number**
IR.TUMS.IKHC.REC.1396.3867

## Health conditions studied

### 1

**Description of health condition studied**
Laparoscopic bariatric surgery
**ICD-10 code**
Z98.84
**ICD-10 code description**
Bariatric surgery status

### 2

**Description of health condition studied**
postprocedural pain
**ICD-10 code**
G89.18
**ICD-10 code description**
Other acute postprocedural pain

## Primary outcomes

### 1

**Description**
pain score
**Timepoint**
6, 24 and 48 hours post surgery
**Method of measurement**
Visual Analogue Scale

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: The Braun Stimuplex Ainsulated needle will enter the skin from the mid-axillary line between the iliac crest and the rib margin. The needle is advanced to the distance between the internal and transverse oblique muscles of the abdomen using a laparoscopic camera and under the direct supervision of a surgeon, and then anesthesia is injected into patients in this area. In this injection, 0.5% marcain solution at the rate of 0.5 mg per kg of body weight will be used.

**Category**
Treatment - Devices

### 2

**Description**
Control group: The Braun Stimuplex Ainsulated needle will enter the skin from the mid-axillary line between the iliac crest and the rib margin. The needle is advanced to the distance between the internal and transverse oblique muscles of the abdomen using a laparoscopic camera and under the direct supervision of a surgeon, and then normal saline is injected into patients in this area.

**Category**
Placebo

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Imam khomeini hospital

**Full name of responsible person**
Mohammadhadi Bahri

**Street address**
Imam Khomeini Hospital Complex, Tehran, Iran

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Tehran

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m.bahri@abzums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
Tehran University of Medical Sciences

**Full name of responsible person**
Mohammadali Sahraeian

**Street address**
sixth floor, Vice Chancellor for Research and Technology, University Center Organization, corner of Ghods Street, Keshavarz Boulevard

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**Province**
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1417613151

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+98 21 8163 3686

**Email**
vcr@tums.ac.ir

**Grant name**

**Grant code / Reference number**

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

**Title of funding source**
Tehran 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**
Tehran University of Medical Sciences

**Full name of responsible person**
Mohammadadi Bahri

**Position**
assistant professor

**Latest degree**
Specialist

**Other areas of specialty/work**
General Surgery

**Street address**
Imam Khomeini Hospital complex, Tehran, Iran

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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Assistant professor

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Specialist

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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 is potentially shareable after unidentified individuals

**When the data will become available and for how long**
The access period starts 3 months after the results are published

**To whom data/document is available**
It will be available only to researchers working in academic and scientific institutions

**Under which criteria data/document could be used**
The reason for the need for data to be decided

**From where data/document is obtainable**
Mohammadhadi Bahri m.bahri@abzums.ac.ir

**What processes are involved for a request to access data/document**
An email must be sent with the reason for the need for data and their email will be answered within 2 weeks.

**Comments**