

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### comparison of two techniques for Transverse Exposure on the cesarean section process in obese patients (Innovative versus routine technique).

#### Protocol summary

##### Summary

Objective: comparison of two techniques for Transverse Exposure on the cesarean section process in obese patients (Innovative versus routine technique). Study design: Clinical trial study by random selection samples via single blind method from obese patients who are candidate for cesarean section in one hospital and will be randomly allocate into two groups (intervention and control) .then we will compare effect of two tecnique on the surgical process. Samples: 130 people (65 participants in each group) with inclusion creteria: no history of numerous surgery, heart diseases and respiratory problems and exclusion creteria: The creation of any complication in duration of surgery and anaesthesia. Intervention: In the intervention method, we will use an innovative method by a simple tool made of two non penetrating towel clips and a suction tube for lifting the abdominal muscles. This approach not only lifts and pulls the abdominal muscles, but also decreases pressure on diaphragm and thorax. After prepping and draping, by using two non penetrating towel clips, the abdominal skin is held in lateral areas. Then a suction tube is passed from the rings of the clips and lift toward up and attach to the stand of anesthesia screen. By applying this method, the sagging abdominal muscles will be away of the working area. In control group will use adhesive tape. Independed variable (interventions): Intervention 1: inovative technique for Transverse Exposure Intervention2: routine tecniques for Transverse Exposure by adhesive tape Depended variable (primary outcomes): surgical process includes duration between anesthesia induction and surgical incision, the baby exit time, the duration time between the baby exit and wound suture and the surgery duration time. The blood loss will be quantified by counting the sponges which are consumed during surgery. Secondary outcome: satisfaction of gynecologist and scrub.

#### General information

##### Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT2015083018553N3**

Registration date: **2015-10-24, 1394/08/02**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-10-24, 1394/08/02

##### Registrant information

###### Name

Leila Sadati

###### Name of organization / entity

Alborz Universty of Medical Scincences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 26 3253 4221

###### Email address

sadati@abzums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research of Alborz University of Medical Sciences

##### Expected recruitment start date

2015-10-02, 1394/07/10

##### Expected recruitment end date

2016-01-30, 1394/11/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

comparison of two techniques for Transverse Exposure on the cesarean section process in obese patients (Innovative versus routine technique).

### Public title

Different Exposure for Caesarean section in obese patients

### Purpose

Supportive

### Inclusion/Exclusion criteria

Inclusion criteria: admission for doing cesarean section for the first or second time; no history of lung and heart diseases; no history of bleeding disorders; surgery performed by surgeons with comparable experience who often do cesarean sections by similar method and in similar time frame Exclusion criteria: Occurrence of intraoperative complications during surgery such as bleeding; severe muscle adhesion which leads to prolong surgical procedure

### Age

To 45 years old

### Gender

Female

### Phase

N/A

### Groups that have been masked

No information

### Sample size

Target sample size: 130

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Single blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

Randomization will be done using the enclosed envelope

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Alborz university of medical sciences

##### Street address

Department of poone. 45metri golshahr ST. Shahid beheshti ST.

##### City

Karaj

### Postal code

### Approval date

2015-08-26, 1394/06/04

### Ethics committee reference number

Abzums.rec.1394.47

## Health conditions studied

### 1

#### Description of health condition studied

obesity

#### ICD-10 code

Y60.0

#### ICD-10 code description

During surgical operation

## Primary outcomes

### 1

#### Description

duration time between of anesthesia induction and surgical incision

#### Timepoint

after intervention

#### Method of measurement

Calculate the time in minutes

### 2

#### Description

the duration time between the baby exit and wound suture

#### Timepoint

after intervention

#### Method of measurement

calculate time in minute

### 3

#### Description

counting the sponges which are consumed during surgery for estimation of bleeding

#### Timepoint

after intervention

#### Method of measurement

counting and Weighting of sponges

## Secondary outcomes

### 1

#### Description

among of satisfaction

#### Timepoint

after intervention

#### Method of measurement

question

## Intervention groups

1

### Description

Intervention: use of simple tool made of two non penetrating towel clips and a suction tube for lifting the abdominal muscles

### Category

Other

2

### Description

Control:use of adhesive tape for lifting the abdominal muscles as a routine method .

### Category

Other

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

kamali hospital

#### Full name of responsible person

dr banafsheh mashak

#### Street address

Kamali hoapital. ShohadaSQ. GazvinST. Karaj.

#### City

Karaj

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Vice chancellor for research of Alborz university of medical sciences

#### Full name of responsible person

Mohammad qaravi

#### Street address

Poone department.45 GolshahrSt. Karaj

#### City

Karaj

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Vice chancellor for research of Alborz university of medical sciences

### Proportion provided by this source

100

### Public or private sector

*empty*

### Domestic or foreign origin

*empty*

### Category of foreign source of funding

*empty*

### Country of origin

### Type of organization providing the funding

*empty*

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Alborz university of medical sciences

#### Full name of responsible person

leila sadati

#### Position

Faculty member

#### Other areas of specialty/work

#### Street address

Faculty member,Golestan6 Ave, Baqestan ST, karaj

#### City

karaj

#### Postal code

#### Phone

+98 26 3434 9802

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#### Email

sadati@abzums.ac.irmashakbanafsheh@yahoo.com

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### Contact

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Faculty member

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## Person responsible for updating data

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Alborz university of medical sciences

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KARAJ

**Postal code****Phone**

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**Fax**

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**Email**

sadati@abzums.ac.ir

**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*