

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 includs 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

Fax

+98 26 3434 9802

Email

sadati@abzums.ac.irmashakbanafsheh@yahoo.com

Web page address

Person responsible for scientific 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

Paramedicin Faculty. Golestan6Ave. Baqestan ST.Karaj.

City

Karaj

Postal code

Phone

+98 26 3434 9802

Fax

+98 26 3434 9802

Email

sadati@abzums.ac.ir

Web page address

Person responsible for updating data

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**

Paramedicin Faculty,Golestan6 Ave,Baghestan ST.

City

KARAJ

Postal code**Phone**

+98 26 3434 9802

Fax

+98 26 3434 9802

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