

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Comparing the effects of conventional surgery with resection of a layer of dermis and epidermis on decreasing the rate of surgical wound infection and dehiscence in high risk patients operated for obstetric or gynecologic conditions

#### Protocol summary

##### Summary

The main goal of this study is to determine the effects of resection of a layer of derm and epiderm on reducing surgical wound infection and dehiscence in high risk patients for these complications. A randomized single blind clinical trial will be enrolled in Talegani and Alzahra hospital of Tabriz-Iran. The researcher or the surgeon, in contrast of the patient, will be aware of the technique of the operation for each patient. In this study we will compare the excision of a thickness of 0.5-1 cm of cutaneous and subcutaneous tissue from each side of the surgical wound with the traditional closing of the subcutaneous and cutaneous tissue. Seven hundred and forty women candidate of cesarean or other gynecologic operations with these inclusion criteria: moderate to severe obesity, diabetes, suppressed immunity, systemic and chronic illnesses, cesarean section for meconium defecation, ruptured membrane, prolonged labor and dystocia, prolonged operation and exclusion criteria: bleeding illnesses, cardiovascular diseases or critical conditions requiring to urgently terminate the surgery, active infection like bacteremia, septicemia, pelvic or abdominal abscess, gynecologic cancers will be studied. They will be divided randomly into two groups of 370 by Rand List software. The two groups will be followed for ten days after the surgery by physical examination for signs of infection like erythema, tenderness, discharge and dehiscence. The data will be analyzed with SPSS 15 to demonstrate the rule of this technique in reducing wound infection.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201206165485N3**

Registration date: **2013-02-03, 1391/11/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-02-03, 1391/11/15

##### Registrant information

###### Name

Nazli Navali

###### Name of organization / entity

Tabriz University of Medical Sciences, Faculty of Medecine

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1330 2879

###### Email address

navalin@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tabriz University of Medical Sciences, Research Deputy, Women Health Research Center

##### Expected recruitment start date

2012-07-05, 1391/04/15

##### Expected recruitment end date

2012-12-06, 1391/09/16

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparing the effects of conventional surgery with resection of a layer of dermis and epidermis on decreasing the rate of surgical wound infection and dehiscence in high risk patients operated for obstetric or gynecologic conditions

## Public title

resection of a layer of skin and decreasing surgical wound infection and dehiscence

## Purpose

Prevention

## Inclusion/Exclusion criteria

Inclusion criteria: patient with moderate to severe obesity (BMI=30-40) , subcutaneous fat thickness over 5 cm, diabetes, suppressed immunity, systemic and chronic illnesses, cesarean section for meconium defecation, ruptured membrane, prolonged labor and dystocia, cesarean lasting more than 2 hours, gynecologic operations lasting more than 3 hours, presence of scars in the operative field Exclusion criteria: patient with bleeding illnesses, cardiovascular diseases or critical conditions requiring to urgently terminate the operation, active infection like bacteremia, septicemia, pelvic or abdominal abscess, chorioamnionitis, acute PID, severe bleeding, cancer

## Age

From **15 years** old to **75 years** old

## Gender

Female

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **740**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

##### Street address

Research Deputy of Tabriz University of Medical

Sciences, University of Tabriz, Golgasht street

#### City

Tabriz

#### Postal code

#### Approval date

2012-06-13, 1391/03/24

#### Ethics committee reference number

5/4/2828

## Health conditions studied

### 1

#### Description of health condition studied

wound infection

#### ICD-10 code

O86.0, T8

#### ICD-10 code description

Disruption of operation wound, Infection of obstetric surgical wound

## Primary outcomes

### 1

#### Description

wound infection

#### Timepoint

third and tenth of the operation

#### Method of measurement

physical examination

## Secondary outcomes

### 1

#### Description

wound dehiscence

#### Timepoint

third and tenth day of the operation

#### Method of measurement

physical examination

## Intervention groups

### 1

#### Description

In the study group, at the end of the operation, that is done by an obstetrics and gynecology resident, after closing the fascia, a layer of 0,5-1 cm of the skin and subcutaneous tissue is excised with a scalpell all the length of the wound and then the subcutaneous tissue and the skin is closed.

#### Category

Treatment - Surgery

### 2

#### Description

In the control group the skin and subcutaneous tissue is

closed routinely without excising them.

### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Alzahra Hospital

**Full name of responsible person**

Dr.Nazli Navali

**Street address**

South Artesh Street

**City**

Tabriz

### 2

#### Recruitment center

**Name of recruitment center**

Talegani Hospital

**Full name of responsible person**

Dr.Nazli Navali

**Street address**

Rahahan Square

**City**

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice chancellor for research, Women's Reproductive Health Research Center

**Full name of responsible person**

Dr.Elahe Saheb Olad Madarec

**Street address**

South Artesh Street

**City**

Tabriz

**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, Women's Reproductive Health Research Center

**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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Nazli Navali

**Position**

assistant professor/ board certificate of obstetrics and gynecology

**Other areas of specialty/work**

**Street address**

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**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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## Person responsible for updating data

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Tabriz University of Medical Sciences

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**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*