

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effect of spray silver nano-particles (Nyvasha) on cesarean section wound healing in women

#### Protocol summary

##### Summary

The present study analyses the effect of silver nano-particles spray on healing of caesarian section wound. This study is done on 90 women referred to Omol-Banin and Imam Reza educational hospital of Mashhad for caesarian section surgery. The women's consent to participate in this research has been acquired. The groups under research are chosen on the basis of entry criterion (by available sampling method) and, then, based on a random allocation method (by the use of SPSS software), they fall into two intervention and one control group. Inclusion criteria include: Patient's consent to participate in this study; have minimum level of literacy; iranian; term pregnancy (37-42 weeks); 18 to 35 years of age; cesarean with beneath cut; initial cesarean section; body mass index in the range of 18.5-25 in early pregnancy; no complications of pregnancy (eclampsia, preclampsia, corioamniotitis, twin pregnancy, poly hydroamnios); no acute or chronic illness; no-disruptive healing (disease i.e diabetes, kidney disease, anemia, liver disease, mental; not having any abnormality in the fetus; non-consumption of drugs and tobacco; non-use of drugs affecting wound healing (glucocorticoids, anticoagulants, immunosuppressant drugs and chemotherapy). Exclusion criteria include: Unwillingness to continue cooperation; major bleeding or need for blood transfusion, hysterectomy and myomectomy with cesarean section; prolonged operation for more than 60 minutes; wound infection; irregular spray use and as directed; complications arising from the use of spray; infancy in NICU.. The first two invention groups receive Nyvasha and placebo spray on the caesarian wound twice a day for 10 consecutive days and each time 3 puffs. The control group does not receive any drugs; they just receive routine care. The researcher sees them on 5th and 10th days after the caesarian section surgery. Just after the caesarian section ( $24 \pm 4$  hours) and on the 5th and 10th days after it, the healing process of sutures are checked out on the basis of Reeda's scale. The

results will be put in Reeda's scale form.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017043033716N1**

Registration date: **2017-11-16, 1396/08/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-11-16, 1396/08/25

##### Registrant information

##### Name

Zakieh Boroumand

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3768 4212

##### Email address

boroumandz941@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for research of Mashhad University of Medical Sciences

##### Expected recruitment start date

2017-07-06, 1396/04/15

##### Expected recruitment end date

2017-10-07, 1396/07/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
The effect of spray silver nano-particles (Nyvasha) on cesarean section wound healing in women

**Public title**  
The effect of Nyvasha spray on cesarean wound healing

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
Inclusion criteria include: Patient's consent to participate in this study; have minimum level of literacy; Iranian; term pregnancy (37-42 weeks); 18 to 35 years of age; cesarean with beneath cut; initial cesarean section; body mass index in the range of 18.5-25 in early pregnancy; no complications of pregnancy (eclampsia, preclampsia , corioamniotitis, twin pregnancy, poly hydroamnios ); no acute or chronic illness; no-disruptive healing (disease i.e diabetes, kidney disease, anemia, liver disease, mental; not having any abnormality in the fetus ; non-consumption of drugs and tobacco; non-use of drugs affecting wound healing (glucocorticoids, anticoagulants, immunosuppressant drugs and chemotherapy). Exclusion criteria include: Unwillingness to continue cooperation; major bleeding or need for blood transfusion, hysterectomy and myomectomy with cesarean section; prolonged operation for more than 60 minutes; wound infection; irregular spray use and as directed; complications arising from the use of spray; infancy in NICU.

**Age**  
From **18 years** old to **35 years** old

**Gender**  
Female

**Phase**  
3

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **90**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Triple blinded

**Blinding description**

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

1

### Ethics committee

#### Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

#### Street address

Ghoreshi building, Daneshgah street

#### City

Mashhad

#### Postal code

9138813944

#### Approval date

2017-06-12, 1396/03/22

#### Ethics committee reference number

IR.MUMS.REC.1396.8

## Health conditions studied

1

### Description of health condition studied

Cesarean

#### ICD-10 code

090.0

#### ICD-10 code description

Disruption of caesarean section wound

## Primary outcomes

1

### Description

Wound healing

#### Timepoint

After cesarean section (24 ±4 hours) and 5th and 10th days after the caesarian section

#### Method of measurement

Reeda Scale

## Secondary outcomes

1

### Description

Pain

#### Timepoint

After cesarean section (24 ±4 hours) and 5th and 10th days after the caesarian section

#### Method of measurement

Pain visual analog scale

## Intervention groups

1

### Description

Intervention group 1: The silver nano-particles spray (Nyvasha) is put at a distance of 10 cm from caesarian wound; three puffs are sprayed on the beginning, middle and end of the wound respectively. Twice a day for 10 consecutive days, and each time 3 puffs, is prescribed.

**Category**

Treatment - Drugs

**2****Description**

Intervention group 2: Spray serum that contains a simple base wash (placebo) is put on caesarean section wound at a distance of 10 cm from the wound. Three puffs are sprayed on the beginning, middle and end of the scar respectively. Twice a day for 10 consecutive days, and each time 3 puffs, is prescribed.

**Category**

Placebo

**3****Description**

Control group: Control group do not receive any drugs; they just receive routine care. The researcher sees them on 5th and 10th days after the caesarian section surgery.

**Category**

Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Omol-Banin Hospital

**Full name of responsible person**

Bibi Hasanzadeh

**Street address**

Ayatolah Bahjat Street

**City**

Mashhad

**2****Recruitment center****Name of recruitment center**

Emam Reza Hospital

**Full name of responsible person**

Ghadernia

**Street address**

Ebnesina Street

**City**

Mashhad

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Ethics committee of Mashhad University of Medical Sciences

**Full name of responsible person**

Mohsen Tafaghodi

**Street address**

Ghoreshi building, Daneshgah street

**City**

Mashhad

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Ethics committee of Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Zakieh Boroumand

**Position**

Midwifery Master

**Other areas of specialty/work****Street address**

Ebnesina Street, School of Nursing and Midwifery

**City**

Mashhad

**Postal code****Phone**

+98 51 3768 4212

**Fax****Email**

Boroumandz941@mums.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Nahid Golmakani

**Position**

Midwifery Master, Assistant Professor

**Other areas of specialty/work****Street address**

Ebnesina Street, Mashhad

**City**

Mashhad

**Postal code**

9137913199

**Phone**

+98 51 3859 1511

**Fax**

+98 51 1859 7313

**Email**

Golmakanin@mums.ac.ir

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Zakieh Boroumand

**Position**

Midwifery Master

**Other areas of specialty/work**

**Street address**

Ebnesina Street, School of Nursing and Midwifery

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+98 51 3768 4212

**Fax**

**Email**

Boroumandz941@mums.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*