

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 ± 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

City

Mashhad

Postal code

Phone

+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