Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

The effect of VitaNit wound healing method in cosmetic outcomes and healing of upper limb orthopedics surgical wound

Protocol summary

Study aim
The effect of VitaNit wound healing method in cosmetic outcomes and healing of upper limb orthopedics surgical wound

Design
Clinical trial with a control group, with parallel groups, without blinding, randomized in block method, phase 3 on 68 patients.

Settings and conduct
This study aims to investigate the effect of the VitaNit wound healing method on the aesthetic results and wound healing of upper limb orthopedic surgery on 68 upper limb surgery patients in Valiasr Arak Hospital. The patients were randomly divided into two intervention and control groups. The intervention group receives the treatment of withanitis and the control group receives the routine treatment. The study is unblinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Upper limb surgery except clavicle surgery 2. Age between 18-60 years 3. Living in Arak or being able to attend all visits exclusion criteria: 1. Smoking 2. Weakness of immunity: use of corticosteroids, chemotherapy drugs and AIDS. 3. Chronic kidney problems 4. Diabetes 5. Blood problems (anemia-polycythemia-...) 6. Being included in special groups (pregnancy-prison) 7. Skin diseases such as eczema, psoriasis 8. Peripheral vascular disease 9. Allergy to vitamin C or nitroglycerin 10. Chronic liver diseases (hepatitis and cirrhosis) 11. Connective tissue disease and rheumatology

Intervention groups
Intervention: They use a combination of vitamin C and TNG spray. Control: They perform frequent dressing and washing with normal saline.

Main outcome variables
Wound size, wound healing speed, wound appearance, scar size, scar appearance characteristics

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221218056851N1**
Registration date: **2023-07-19, 1402/04/28**
Registration timing: **prospective**

Last update: **2023-07-19, 1402/04/28**
Update count: **0**

Registration date
2023-07-19, 1402/04/28

Registrant information

Name
Mona hamedi tabar

Name of organization / entity

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Iran (Islamic Republic of)

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+98 86 3417 3503

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-08-21, 1402/05/30

Expected recruitment end date
2023-12-22, 1402/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of VitaNit wound healing method in cosmetic outcomes and healing of upper limb orthopedics surgical wound

Public title
The effect of the VitaNit method on upper limb orthopedic surgery wounds
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Upper limb surgery except clavicle surgery . Age between 18-60 years old Residence in Arak city or the possibility of patient presence for all visits.
Exclusion criteria:
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **68**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization using the block method using blocks of four, 68 people were randomized into two groups in blocks of four and were assigned to intervention and control groups.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research ethics committees of Arak University of Medical Sciences
Street address
Arak Univercity of Medical Science, Arak
City
Arak
Province
Markazi
Postal code
3848176341
Approval date
2023-05-30, 1402/03/09
Ethics committee reference number
IR.ARAKMU.REC.1402.055

Health conditions studied

1

Description of health condition studied
Orthopedics surgical wound
ICD-10 code
Z47.9
ICD-10 code description
Orthopaedic follow-up care, unspecified

Primary outcomes

1

Description
Wound size
Timepoint
Immediately and 1, 2, 3, 4 weeks later
Method of measurement
Wound area is measured using ImitoMeasure v:2.0.0.18 mobile application.

2

Description
Speed of wound healing
Timepoint
Immediately and 1, 2, 3, 4 weeks later
Method of measurement
Measured using ImitoMeasure v:2.0.0.18 mobile application.

3

Description
Wound appearance
Timepoint
Immediately and 1, 2, 3, 4 weeks later
Method of measurement
With REEDA scoring system

4

Description
Scar size
Timepoint
Immediately and 1, 2, 3, 4 weeks later
Method of measurement
If a scar is created, it is measured using the ImitoMeasure v:2.0.0.18 mobile application.

5

Description
Appearance features of Oscar
Timepoint
Immediately and 1, 2, 3, 4 weeks later

Method of measurement
With VSS scoring system

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The combination of vitamin C and TNG spray is used. How to make the product is as follows: to make a nitroglycerin spray, about 50 mg of nitroglycerin is poured into a spray and one puff is used for every 10 cm wound (each puff contains one to two mg of nitroglycerin). And to make vitamin C spray, 10 injection vials of vitamin C with a volume of 5 ml containing 500 mg of vitamin C are poured into the syringe and one puff of the spray is used for every 10 cm of the wound (each puff contains 20 to 40 mg of vitamin C). Patients use sprays after being taught how to use them after the operation (on the day of discharge). Patients need to use this spray 4 times a day (every 6 hours) during the first 2 weeks. The wound area is sprayed (one puff for every ten centimeters) so that the surface is completely covered, and then vitamin C spray is sprayed on the wound (one puff for every 10 centimeters), and after an hour, the drape is removed and normal dressing is applied. is done 6 hours later, this work is done again, and in the next two weeks, the patient uses both sprays once every hour in the order mentioned, but there is no need for dressing.
Category
Treatment - Drugs

2

Description
Control group: receives only routine treatment (repeated dressing and washing with normal saline).
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr hospital
Full name of responsible person
Mohammad Reza Bozorgmanesh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Mona Hamedi Tabar
Position
General physician
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available