

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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 hamed i tabar

Name of organization / entity

Country

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		2023-05-30, 1402/03/09
Public title The effect of the VitaNit method on upper limb orthopedic surgery wounds		Ethics committee reference number IR.ARAKMU.REC.1402.055
Purpose Treatment		Health conditions studied
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:		1 Description of health condition studied Orthopedics surgical wound ICD-10 code Z47.9 ICD-10 code description Orthopaedic follow-up care, unspecified
Age From 18 years old to 60 years old		Primary outcomes
Gender Both		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.
Phase 3		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.
Groups that have been masked <i>No information</i>		3 Description Wound appearance Timepoint Immediately and 1, 2, 3, 4 weeks later Method of measurement With REEDA scoring system
Sample size Target sample size: 68		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.
Randomization (investigator's opinion) Randomized		5 Description Appearance features of Oscar Timepoint Immediately and 1, 2, 3, 4 weeks later
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		

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 Hamed Tabar

Position

General physician

Latest degree

Medical doctor

Other areas of specialty/work

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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