Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Silicone Gel Versus Contractubex Gel effect on upper-extremity postsurgical Scars

Protocol summary

Study aim

Determination of Silicone Gel Versus Contractubex Gel effect on upper-extremity post surgical Scars

Design

Randomized, Double-blind, parallel, clinical trial, designed during one years on 120 upper extremity sharp injury patients from January 2018 to January 2019 in 15 Khordad Hospital (Tehran, Iran), affiliated to Shahid Beheshti University of Medical Sciences.

Settings and conduct

In this double-blind trial study that conduct on Sharp injury, to the upper extremity patients who referred to the 15 khordad Hospital of Shahid Beheshti University of Medical Sciences, the participant, investigator and outcomes assessor were not familiar with the groups. From the day of suture removal (ten day), the treatment was applied one time daily in group one and two time daily in group 2, half a fingertip for every 10 cm of wound length (equivalent to one gram of contractubex gel or silicone gel), for 4 months. Group 3 left untreated as control. Patients were followed up for 4 months and outcomes were compared in the three groups between the second week and the sixteenth week.

Participants/Inclusion and exclusion criteria

Sharp injury to the upper extremity patients who referred to the 15 khordad Hospital of Shahid Beheshti University of Medical Sciences

Intervention groups

Intervention 1 (Silicone gel) : Kelo-cort™; Advanced Bio-Technologies, Silverdale, WA, USA) (group 1; 40 patients)
Intervention 2(Onion extract): Contractubex™, Merz Pharma, Frankfurt, Germany) gel (group 2; 40 patients)
Control: Not treated

Main outcome variables

post surgical scar formation assessment using Vancouver scale score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141218020364N10**
Registration date: **2019-05-17, 1398/02/27**
Registration timing: **retrospective**

Last update: **2019-05-17, 1398/02/27**
Update count: **0**

Registration date

2019-05-17, 1398/02/27

Registrant information

Name

Mohhammad Yasin Karami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3839 1385

Email address

karamiy@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-19, 1397/01/30

Expected recruitment end date

2019-01-15, 1397/10/25

Actual recruitment start date

2018-04-19, 1397/01/30

Actual recruitment end date

2019-01-15, 1397/10/25

Trial completion date

2019-05-15, 1398/02/25

Scientific title

Silicone Gel Versus Contractubex Gel effect on upper-extremity postsurgical Scars

Public title
Silicone Gel Versus Contractubex Gel effect on Scar
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
male gender aged between 18-45 year able to read and write informed consent and questionnaire
Exclusion criteria:
mental disorders peripheral vascular diseases acute viral diseases men who developed surgical complications such as wound infection men who had a history of hypertrophic or keloid scarring in upper extremity men who were taking chemotherapeutic agents or other medications that would affect wound healing men who had comorbidities such as contractive skin disorders (e.g., scleroderma) men who had allergy to silicone or onion
Age
From **18 years** old to **45 years** old
Gender
Male

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **150**
Actual sample size reached: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization using drawing sealed envelopes and a computer-based table of randomization
Blinding (investigator's opinion)
Double blinded
Blinding description
In this double-blind trial study, the participant, investigator and outcomes assessor were not familiar with the groups. we used identify code for each patient and also used unlabeled medication with same box shape for each group. The safety and data monitoring committee was informed about the study groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee on Research in Shahid Beheshti University of Medical Sciences
Street address
Shahid Aarabi
City
Tehran
Province
Tehran
Postal code
1985717434
Approval date
2018-04-15, 1397/01/26
Ethics committee reference number
IR.SBMU.RETECH.REC.1397.458

Health conditions studied

1

Description of health condition studied
Keloid scar
ICD-10 code
L91.0
ICD-10 code description
Hypertrophic scar

Primary outcomes

1

Description
Height of scar
Timepoint
4 months after the start of intervention
Method of measurement
With a ruler and scoring based on the Vancouver scar scale

2

Description
Vascularity of scar
Timepoint
4 months after the start of intervention
Method of measurement
Observation and evaluation of post-white fill velocity due to pressure and scoring based on the Vancouver scar scale

3

Description
Pliability of scar
Timepoint
4 months after the start of intervention
Method of measurement

Touch and scoring based on the Vancouver scar scale

4

Description
Pigmentation of scar
Timepoint
4 months after the start of intervention
Method of measurement
view and scoring based on the Vancouver scar scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Silicone gel (Kelo-cort™; Advanced Bio-Technologies, Silverdale, WA, USA) Administration of silicone gel ointment on scar from the day of suture removal (ten day), the treatment was applied one time daily, half a fingertip for every 10 cm of wound length (equivalent to one gram of silicone gel), for 4 months.
Category
Prevention

2

Description
Intervention group 2: Contractubex™, Merz Pharma, Frankfurt, Germany. Administration of Contractubex gel ointment on scar from the day of suture removal (ten day), the treatment was applied twice daily, half a fingertip for every 10 cm of wound length (equivalent to one gram of gel), for 4 months.
Category
Prevention

3

Description
Control group: not-treated
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
15 Khordad Hospital
Full name of responsible person
Esmail Hassanpour
Street address
Karimkhan
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 2243 9780
Email
esmail_hasanpour@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Shahid Aarabi
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 2243 9331
Email
zarghi@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Esmail Hassanpour
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Plastic Surgery
Street address
Karimkhan

City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 2243 9780
Email
esmail_hassanpour@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Esmail hassanpour
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Plastic Surgery
Street address
Karimkhan
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 2243 9780
Email
esmail_hassanpour@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Esmail Hasanpour
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Plastic Surgery
Street address
Karimkhan
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 2243 9780
Email
esmail_hassanpour@yahoo.com

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
Not applicable
Data Dictionary
Not applicable