

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Mohammad 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