Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Efficacy of Topical Silicone 5% Hydrogel versus Topical Hydrocortisone 1% Ointment in Keloid Treatment measured using POSAS Score. A Randomized, Double-Blind Study

Protocol summary

Study aim

To compare the efficacy between Silicone 5% Hydrogel and Hydrocortisone 1% ointment in keloid treatment

Design

Single hospital-based center, Parallel, Double Blind, Randomized Controlled Study

Settings and conduct

The participants were allocated to Silicone 5% Hydrogel or Hydrocortisone 1% ointment group over 12 weeks. POSAS was used for clinical evaluation. The investigator and the participants were not aware of the ingredients in the topicals.

Participants/Inclusion and exclusion criteria

Inclusion criteria : - 18 years old and above - have at least two keloid scars on the same anatomical site or having one large keloid scar exceeding 5cm (large scar was divided into two parts for two different treatment arms) (more than six months to than five years) - Available for 12 weeks for the study - Educationally competent to understand the Patient and Observer Scar Assessment Scale (POSAS) used for assessment Exclusion criteria: - History of allergy or hypersensitivity responses to any component of the medications or dressing used in the study - Active dermatoses superimposed on the keloid and skin infection - connective tissue disorders, diabetes mellitus, pregnant, lactating mother - Keloid shorter than eight weeks

Intervention groups

Treatment: received topical Silicone 5% Hydrogel on keloid scar for 12 weeks Control: received hydrocortisone 1% ointment on keloid scare for 12 weeks

Main outcome variables

Patient scale score 1-10 for scar using POSAS involved: Pain, itch, discolouration, hardness, thickness, and difference in comparison to the normal skin Observer scale score 1-10 for scar using POSAS involved: vascularity, pigmentation, thickness, relief, pliability, surface area, Keloid assessment: tenderness, site, size, surface, shape, edge, consistency, fluid thrill, pulsatility, mobility and movement with inspiration whether it can get above the mass.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220727055565N1**
Registration date: **2022-09-28, 1401/07/06**
Registration timing: **retrospective**

Last update: **2022-09-28, 1401/07/06**
Update count: **0**

Registration date

2022-09-28, 1401/07/06

Registrant information

Name
Liyana Dhamirah Aminuddin
Name of organization / entity
Universiti Teknologi Mara
Country
Malaysia
Phone
+60 3-6126 5000
Email address
liyanadhamirah@uitm.edu.my

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-13, 1397/08/22

Expected recruitment end date

2019-11-12, 1398/08/21

Actual recruitment start date
2018-11-21, 1397/08/30
Actual recruitment end date
2019-11-20, 1398/08/29
Trial completion date
2019-11-20, 1398/08/29

Scientific title
Efficacy of Topical Silicone 5% Hydrogel versus Topical Hydrocortisone 1% Ointment in Keloid Treatment measured using POSAS Score. A Randomized, Double-Blind Study

Public title
Efficacy of Topical Silicone 5% Hydrogel versus Topical Hydrocortisone 1% Ointment in Keloid Treatment measured using POSAS Score. A Randomized, Double-Blind Study
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 or above Educationally competence able to participate in the study for 12 weeks At least two keloid scars on the same anatomical site or having one large keloid scar exceeding 5cm
Exclusion criteria:
History of allergy or hypersensitivity responses to any component of the medications or dressing used in the study Active primary or secondary dermatoses superimposed on the keloid Active skin infection, connective tissue disorders and diabetes mellitus. Patients who were educationally incompetence and were not able to understand the Patient and Observer Scar Assessment Scale (POSAS) Had a history of keloid treatment (shorter than eight weeks) Pregnant Lactating Keloid less than 8 weeks
Age
From **18 years** old
Gender
Both

Phase
1
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **32**
More than 1 sample in each individual
Number of samples in each individual: **16**
Treatment group was applied with silicone 5% hydrogel and the Hydrocortisone 1% ointment was applied in the comparison group for 12 weeks. Both Silicone 5% Hydrogel and Hydrocortisone 1% ointment were put in the container A and B of 15 g. Only the third party know what was the contained on the container.
Actual sample size reached: **28**
More than 1 sample in each individual
Actual sample size in each individual: **14**
Treatment group was applied with silicone 5% hydrogel and the Hydrocortisone 1% ointment was applied in the comparison group for 12 weeks. Both Silicone 5% Hydrogel and Hydrocortisone 1% ointment were put in the container A and B of 15 g. Only the third party know what was the contained on the container.
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization. The patients was allocated to Silicone 5% Hydrogel or Topical Hydrocortisone 1% Ointment group by simple randomization using computer generated sequence. The total number of patients needed in this study was entered to the EpiInfo6 software. Then, the software generated a list of number to which group the patients will be
Blinding (investigator's opinion)
Double blinded
Blinding description
Double blinding was applied in this study. The investigator and participants were blinded. Only the manufacturer (third party) has the information on the type of treatment received by participants (whether intervention and placebo). The third party provided the Silicone 5% Hydrogel and the Topical Hydrocortisone 1% Ointment. Both Silicone 5% Hydrogel and hydrocortisone 1% ointment were prepared in the same colour and appearance.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethic Committee, Universiti Technologi MARA
Street address
Research Management Centre, Universiti Teknologi MARA
City
Shah Alam
Postal code
40450
Approval date
2018-11-13, 1397/08/22
Ethics committee reference number
REC/344/18

Health conditions studied

1

Description of health condition studied
Keloid Scar

ICD-10 code
L91.0
ICD-10 code description
Keloid scar

Primary outcomes

1

Description
To compare the effects of "keloid scar condition"
Timepoint
at baseline (before intervention), at week-4, at week-8 and week-12 (4 weeks interval) after completion of the intervention
Method of measurement
Validate scoring tool Patient and Observer Scar Assessment Scale (POSAS)

2

Description
To compare the effects of "pigmentation keloid scar"
Timepoint
at baseline (before intervention), at week-4, at week-8 and week-12 (4 weeks interval) after completion of the intervention
Method of measurement
Mexameter

Secondary outcomes

empty

Intervention groups

1

Description
"Intervention group": The patients were given SILHYD. SILHYD was prepared by the manufacturer as a cream contain of silicone 5% hydrogel, The cream was applied 0.5mg, once daily at the keloid scar pigmentation topically on the keloid scar pigmentation for 12 weeks duration.
Category
Treatment - Other

2

Description
"Control group": The patients were given hydrocortisone 1% ointment . hydrocortisone 1% ointment was prepared by the manufacturer as a cream contain of hydrocortisone 1%. The cream was applied 0.5mg, once daily at the keloid scar pigmentation topically on the keloid scar pigmentation for 12 weeks duration.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Dermatology Clinic, Faculty Of Medicine, Universiti Teknologi MARA
Full name of responsible person
Liyana Dhamirah Aminuddin
Street address
Universiti Teknologi MARA Campus Sungai Buloh
City
Sungai Buloh
Postal code
47000
Phone
+60 12-648 0020
Email
liyanadhamirah@uitm.edu.my

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Universiti Teknologi MARA
Full name of responsible person
Liyana Dhamirah Aminuddin
Street address
Jalan Hospital
City
Sungai Buloh
Postal code
47000
Phone
+60 12-648 0020
Email
liyanadhamirah@uitm.edu.my
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Universiti Teknologi MARA
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
Universiti Teknologi MARA
Full name of responsible person
Liyana Dhamirah Aminuddin
Position
Consultant Dermatologist
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Universiti Teknologi MARA Sungai Buloh Campus, Jalan Hospital
City
Sungai Buloh
Province
Selangor Darul Ehsan
Postal code
47000
Phone
0061265000
Email
liyanadhamirah@uitm.edu.my

Person responsible for scientific inquiries

Contact
Name of organization / entity
Universiti Teknologi MARA
Full name of responsible person
LIYANA DHAMIRAH AMINUDDIN
Position
Consultant Dermatologist
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Universiti Teknologi MARA, Sungai Buloh Campus
City
Sungai Buloh
Province
Selangor Darul Ehsan
Postal code
47000
Phone
+60 3-6126 5000
Email
liyanadhamirah@uitm.edu.my

Person responsible for updating data

Contact
Name of organization / entity
Universiti Teknologi MARA
Full name of responsible person
Research Ethic Committee, Universiti Technologi MARA
Position
Consultant Dermatologist
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Universiti Teknologi MARA, Sungai Buloh Campus
City
Sungai Buloh
Province
Selangor Darul Ehsan
Postal code
47000
Phone
+60 3-6126 5000
Email
liyanadhamirah@uitm.edu.my

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Efficacy of Topical Silicone 5% Hydrogel versus Topical Hydrocortisone 1% Ointment in Keloid Treatment measured using POSAS Score. A Randomized, Double-Blind Study will be kept for research purpose only
When the data will become available and for how long
Will be kept for 7 years until after completion of study
To whom data/document is available
Only for members of the research
Under which criteria data/document could be used
Research only
From where data/document is obtainable
Principal Investigator
What processes are involved for a request to access data/document
Official letter of request will be needed to state reason(s) for request
Comments
No