Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Evaluation of the efficacy, safety, satisfaction and tolerability of treatment with diluted botulinum toxin A in comparison with intralesional triamcinolone in patients undergone PDL laser for Hypertrophic erythematous scars: A blinded randomized controlled clinical trial

Protocol summary

Study aim
Evaluation of efficacy, safety, satisfaction and tolerability of treatment of erythematous hypertrophic scars by injection of diluted botulinum toxin type A in comparison with triamcinolone injection in patients undergoing PDL laser treatment

Design
Clinical trial with 3 intervention groups, blinded, parallel, randomized, phase 2-3 on 12 patients, randomized by Excel software

Settings and conduct
Patients referred to Hazrat Fatemeh Hospital Laser Clinic with at least 3 hypertrophic erythematous scar lesions will randomly receive one of the following treatments for each lesion: 1. PDL laser (control) 2. PDL laser with botulinum toxin type A. 3. PDL laser with intralesional triamcinolone. In the second and third sessions, all lesions will be treated only with PDL laser and in the fourth session, the lesions will be followed up without any intervention. In each session, all lesions will be imaged. The study will be done as a single blind study. The results of the studies will be evaluated by a blind dermatologist based on the images prepared from the lesions in each session and also the data analysis will be done by a blind statistical expert.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Hypertrophic erythematous scars of at least 3 2. The size of the lesions should be at least 10 × 10 cm2 or have a length of at least 10 cm. 3. The patient has not received any treatment for the lesions in the last two months. Exclusion criteria: Occurrence of allergies or any side effects

Intervention groups
1. PDL laser treatment (control group) 2. PDL laser treatment with injection of diluted botulinum toxin type A. 3. PDL laser treatment with intralesional injection of triamcinolone

Main outcome variables
Effectiveness of treatment using Vancouver scar scale (VSS) scoring method

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220121053776N1**
Registration date: **2022-02-16, 1400/11/27**
Registration timing: **prospective**

Last update: **2022-02-16, 1400/11/27**
Update count: **0**

Registration date
2022-02-16, 1400/11/27

Registrant information

Name
Mohammad Amin Jafari

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-20, 1400/12/01

Expected recruitment end date

2023-05-22, 1402/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy, safety, satisfaction and tolerability of treatment with diluted botulinum toxin A in comparison with intralesional triamcinolone in patients undergone PDL laser for Hypertrophic erythematous scars: A blinded randomized controlled clinical trial

Public title

Comparison of the efficacy of botulinum toxin and triamcinolone in patients with hypertrophic scars treated with PDL laser

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients over 18 years Patients with a confirmed diagnosis of hypertrophic erythematous scars of at least 3 The size of the mentioned lesions should be at least 10 × 10 cm or have a length of at least 10 cm The patient is not pregnant or breast feeding The patient has not received any treatment for lesions such as laser, topical or injectable corticosteroids in the past two months The patient has no underlying diseases that lead to the healing process of the scar; Such as diabetes or weakened immune system The patient's cooperation in performing medical interventions and referring to all treatment sessions

Exclusion criteria:

Occurrence of pregnancy during treatment or follow-up period The occurrence of allergies or any side effects to one of the therapeutic interventions that prevent further treatment Diagnosis of malignancy or systemic disease during treatment or follow-up period The appearance of bacterial or viral skin diseases during treatment or follow-up

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **12**

More than 1 sample in each individual

Number of samples in each individual: **3**

The sample size was a total of 34, considering that the patients are divided into three groups, 12 cases will be placed in each group. Equivalently, considering that in this study patients with at least 3 lesions were included and for the lesions of each patient one of the mentioned treatment methods will be performed randomly, in this study a total of 36 lesions (12 lesions in each group), In other words, 12 patients will be included.

Randomization (investigator's opinion)

Randomized

Randomization description

Using simple randomization method, patients' lesions are divided into 3 groups, so that out of 36 sealed envelopes, one envelope is randomly selected for each lesion. Inside each envelope is the letter A or B or C.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the clear difference between the mentioned therapeutic interventions, it is not possible to blind the therapist and patients and the study will be performed as a single blind study. The data will be evaluated by a blind evaluator based on the images prepared from the lesions in each session and also the data analysis will be done by a blind statistical expert.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of medical scinces

Street address

Hazrat Rasool Akram hospital, Mansoori avenue, Sattarkhan street, Tehran, Iran

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Province

Tehran

Postal code

1445613131

Approval date

2021-11-16, 1400/08/25

Ethics committee reference number

IR.IUMS.FMD.REC.1400.487

Health conditions studied

1

Description of health condition studied

Hypertrophic erythematous scar

ICD-10 code

L91.0

ICD-10 code description

Hypertrophic scar

Primary outcomes

1

Description
Effectiveness of treatment
Timepoint
Three months after the first treatment session
Method of measurement
By using Vancouver scar scale (VSS) scoring method

Secondary outcomes

1

Description
Safety
Timepoint
One, two and three months after the first treatment session
Method of measurement
Questions about possible side effects of treatment

2

Description
Tolerability
Timepoint
One, two and three months after the first treatment session
Method of measurement
Question from the patient

3

Description
Satisfaction
Timepoint
One, two and three months after the first treatment session
Method of measurement
Based on patient scoring

Intervention groups

1

Description
Control group: Treatment with PDL: Before the intervention, cleaning the lesion by using normal saline impregnated gas will be done. Then, 60 minutes before laser treatment, a local anesthetic cream containing lidocaine 2.5% and prilocaine 2.5% (Xyla-P, Tehran Chemie, Tehran, Iran) will be applied to the lesion. At the end of 60 minutes, the local anesthetic cream will be removed using an alcohol swab. Then PDL laser using Alexandrite Deca laser device (Synchro VasQ, Deka, Florence, Italy) with a pulse of 595 nm, spot size 7 mm, single duration of half a millisecond and power of 6.5 J / cm2 with 100 shots per area A 10 × 10 cm square lesion will be applied. PDL laser will be applied in all treatment groups and in the first three sessions.
Category
Treatment - Devices

2

Description
Intervention group 1: PDL treatment with injection of diluted botulinum toxin type A: In the second group, in addition to the PDL laser, in the first session, the injection of botulinum toxin type A of Dysport manufacturer (Speywood Pharmaceuticals Ltd., Maidenhead, UK) will be performed in diluted form immediately after laser treatment. Each vial contains Clostridium botulinum toxin type A hemoglutin complex with 125 micrograms of human albumin and 2.5 mg of lactose. Each vial has 500 units of dysport and dilution will be performed in 2.5 ml of normal saline to achieve a concentration of 200 units per ml. The toxin will then be injected at a dose of 2.5 units per cubic centimeter into the lesion, so that the total number of units injected into each lesion does not exceed 100 units.
Category
Treatment - Other

3

Description
Intervention group 2: PDL treatment with intralesional injection of triamcinolone: In the third group, in addition to PDL laser, in the first session, intralesional triamcinolone will be performed immediately after laser treatment. For this purpose, 40 mg / 1 triamcinolone ampoule is used (Exir Co., Tehran, Iran) which is diluted with 2% lidocaine solution (Xylopen, Exir co., Tehran, Iran) in equal volume and in a concentration of 20 Mg in 1 ml will be used. Finally, 1 ml (20 mg of triamcinolone) per 100 cm 2 of the lesion will be injected.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Fatemeh hospital
Full name of responsible person
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Sponsors / Funding sources

1

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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
Iran 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

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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
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Not applicable