Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The efficacy and safety of atmospheric pressure plasma versus low-level laser therapy on chronic wounds (including dystrophic epidermolysis bullosa)

Protocol summary

Study aim

The efficacy and safety of atmospheric pressure plasma versus low-level laser therapy on chronic wounds (including dystrophic epidermolysis bullosa)

Design

In this clinical trial, 6 patients with Dystrophic EB will be included and in each patient 5 wounds will be randomly selected for different kinds of treatment. In each patient, 2 wounds will be treated with plasma, 2 wounds with low level laser and one was dressed with standard wound care as the control.

Settings and conduct

The quality of wound healing will be assessed by evaluation of wound size and also a designed qualitative wound score (QWS), which evaluate the healing by scoring changes in four parameters as follows: (i) size (scores of 0, 1, and 2, indicating decreased size, no change or increased size, respectively); (ii) odour (0, no and 1, yes); (iii) exudate (scores of 0, 1 and 2 indicating none, mild and moderate to severe, respectively); and (iv) redness (scores of 0, 1 and 2 indicating none, pink and red, respectively). A dermatologist who is unaware of the assigned treatment for each lesion, recruit to assess the lesions before treatment, after each session of treatment (during treatment), 2, 6 and 12 weeks after treatment

Participants/Inclusion and exclusion criteria

- Inclusion criteria: Dystrophic EB patients with age over 10 years, old chronic wounds over 3 months, Full satisfaction for entrance to the study, without exclusion criteria - Exclusion criteria: Other comorbidities including collagen vascular diseases and vasculitis, coronary artery diseases, active infection, malignancy on the treatment area, Alcoholics and smokers

Intervention groups

Dystrophic EB patients who have old chronic wounds over 3 months with no response to conventional treatments

Main outcome variables

Time of complete wound healing Dermatology Life Quality Index Qualitative wound score (QWS) Recurrence time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160320027109N2**
Registration date: **2018-12-02, 1397/09/11**
Registration timing: **retrospective**

Last update: **2018-12-02, 1397/09/11**
Update count: **0**

Registration date

2018-12-02, 1397/09/11

Registrant information

Name
Fahimeh Abdollahimajd
Name of organization / entity
Skin Research Center
Country
Iran (Islamic Republic of)
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+98 21 2274 1507
Email address
fabdollahimajd@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-04, 1397/08/13

Expected recruitment end date

2018-11-21, 1397/08/30

Actual recruitment start date

2018-01-14, 1396/10/24

Actual recruitment end date

2018-07-22, 1397/04/31

Trial completion date

empty

Scientific title

The efficacy and safety of atmospheric pressure plasma versus low-level laser therapy on chronic wounds (including dystrophic epidermolysis bullosa)

Public title

The efficacy of atmospheric pressure plasma versus low-level laser on chronic wounds (including epidermolysis bullosa)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 10 years old Chronic wounds over 3 months Without exclusion criteria Full satisfaction for entrance to the study

Exclusion criteria:

Other comorbidities including collagen vascular diseases and vasculitis Coronary artery diseases Active infection malignancy in the treatment area Alcoholics and smokers

Age

From **10 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **6**

More than 1 sample in each individual

Number of samples in each individual: **5**

For each patient, 2 wounds for plasma therapy, 2 wounds for laser therapy and 1 wound with standard wound dressing as a control

Actual sample size reached: **6**

More than 1 sample in each individual

Actual sample size in each individual: **5**

For each patient, 2 wounds for plasma therapy, 2 wounds for laser therapy and 1 wound with common wound dressing

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Data analysis will be done by a dermatologist who is unaware of the assigned treatment for each lesion

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Skin Research Center,Shahid Beheshti University of Medical Sciences

Street address

The SBMU SRC (Skin Research Center),Shohada-E-Tajrish Educational Hospital,Qods Sq. ,Tehran, Iran

City

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Province

Tehran

Postal code

1989934148

Approval date

2016-02-02, 1394/11/13

Ethics committee reference number

IR.SBMU.SRC.REC.1394.13

Health conditions studied

1

Description of health condition studied

Dystrophic epidermolysis bullosa

ICD-10 code

Q81.2

ICD-10 code description

Epidermolysis bullosa dystrophica

Primary outcomes

1

Description

The wound size

Timepoint

Before treatment, after each session of treatment (during treatment), 2, 6 and 12 weeks after treatment

Method of measurement

Photography, Qualitative Wound Score, imagej software

Secondary outcomes

1

Description

Quality of life

Timepoint

Before and just after treatment, 12 weeks after the last session of treatment

Method of measurement

the Dermatology Life Quality Index (DLQI)

Intervention groups

1

Description

Intervention group: In each patient, 2 wounds will be selected and treated with plasma twice a week until complete improvement (or average 8 weeks) and the wounds will be evaluated in each session of treatment, 2 , 6 and 12 weeks after the last session of treatment.

Category

Treatment - Other

2

Description

Intervention group: In each patient, 2 wounds will be selected and treated with low level laser twice a week until complete improvement (or average 8 weeks) and the wounds will be evaluated in each session of treatment, 2 , 6 and 12 weeks after the last session of treatment.

Category

Treatment - Other

3

Description

Control group: In each patient, one wound will be selected and treated with standard wound care (as a control) twice a week until complete improvement (or average 8 weeks) and the wounds will be evaluated in each session of treatment, 2 , 6 and 12 weeks after the last session of treatment

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology clinic, Shohada-e Tajrish Hospital

Full name of responsible person

Fahimeh Abdollahimajd

Street address

Shohada-e Tajrish Hospital,Qods Sq. ,Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Skin Research Center, Shahid Beheshti University of Medical Science

Full name of responsible person

Dr Parviz Toossi

Street address

Skin Research Center, Shohada-e Tajrish Hospital, Qods sq, Tehran, Iran

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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

Skin Research Center, Shahid Beheshti University of Medical Science

Proportion provided by this source

40

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

Full name of responsible person

Reza Shakouri

Position

Skin expert of plasma in Fanavar Jam Company

Latest degree

Master

Other areas of specialty/work

Plasma physics

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Person responsible for scientific inquiries

Contact
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Shahid Beheshti University of Medical Sciences
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Position
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Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University
Full name of responsible person
Shirin Samsavar
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Latest degree
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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
Undecided - It is not yet known if there will be a plan to make this available