

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The pilot study of efficacy of topical formulation of Henna (*Lawsonia inermis*)1% in itching sensation and wound healing in patients with epidermolysis bullosa: a non randomized open clinical trial

#### Protocol summary

##### Study aim

Efficacy of Topical Henna Product in Wound Healing and Pruritus in Patients with Epidermolysis Bullosa

##### Design

The clinical trial is without control group and without randomization. The outcome of treatment is evaluated by a physician independent of the study. Patients are evaluated every week for one month.

##### Settings and conduct

Patients entering the study are selected from patients with Epidermolysis bullosa referred to Molecular Dermatology Research Center. The drug is delivered to the patient in 50-gram containers.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients with Epidermolysis Bullosa; 2. Age over 5 years old; 3. Patient or his/her parent's consent to participate in the study\*\*\*\* Exclusion criteria: 1. Patients younger than 5 years old; 2. Patients or their parents not consenting to participate in the study; 3. Positive history of allergic to Henna; 4. Patients with G6PD deficiency (Glucose-6-phosphate dehydrogenase deficiency)

##### Intervention groups

Intervention group includes patients older than 5 years with Epidermolysis Bullosa who received topical product containing 1% henna extract. is that the patient uses 0.5 grams of cream (equivalent to one finger) twice a day in the itchy area and once a day in the wound area

##### Main outcome variables

Score of itching and wound healing

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150825023753N14**

Registration date: **2019-08-31, 1398/06/09**

Registration timing: **retrospective**

Last update: **2019-08-31, 1398/06/09**

Update count: **0**

##### Registration date

2019-08-31, 1398/06/09

##### Registrant information

###### Name

Mohammad Mahdi Parvizi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 3212 5592

###### Email address

parvizim@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-09-23, 1397/07/01

##### Expected recruitment end date

2019-01-20, 1397/10/30

##### Actual recruitment start date

2018-09-23, 1397/07/01

##### Actual recruitment end date

2018-12-21, 1397/09/30

##### Trial completion date

2019-05-05, 1398/02/15

##### Scientific title

The pilot study of efficacy of topical formulation of Henna (*Lawsonia inermis*)1% in itching sensation and wound healing in patients with epidermolysis bullosa: a non randomized open clinical trial

**Public title**

Efficacy of topical formulation of Henna in itching sensation and wound healing in patients with epidermolysis bullosa

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with Epidermolysis Bullosa Age over 5 years old Patient or his/her parent's consent to participate in the study

**Exclusion criteria:**

Patients younger than 5 years old Patients or their parents not consenting to participate in the study Positive history of allergic to Henna Patients with G6PD deficiency (Glucose-6-phosphate dehydrogenase deficiency)

**Age**

From **5 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **7**

Actual sample size reached: **7**

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Single

**Other design features**

Pilot study, without blinding and randomization

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

**Street address**

Shiraz University of Medical Sciences, Zand blv., Shiraz, Fars, Iran

**City**

Shiraz

**Province**

Fars

**Postal code**

7134814336

**Approval date**

2019-08-14, 1398/05/23

**Ethics committee reference number**

IR.SUMS.REC.1398.761

**Health conditions studied****1****Description of health condition studied**

Epidermolysis Bullosa Dystrophica

**ICD-10 code**

Q81.2

**ICD-10 code description**

Epidermolysis bullosa dystrophica

**Primary outcomes****1****Description**

Itching score

**Timepoint**

Once a week until 1 month

**Method of measurement**

Visual Analogue Scale (VAS)

**2****Description**

Percentage of wound healing

**Timepoint**

Percentage of wound healing

**Method of measurement**

Clinical global impression of improvement

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Intervention group includes patients older than 5 years with Epidermolysis Bullosa who received topical product containing 1% henna extract. is that the patient uses 0.5 grams of cream (equivalent to one finger) twice a day in the itchy area and once a day in the wound area

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Molecular Dermatology Research Center

**Full name of responsible person**

Dr. Mohammad Mahdi Parvizi

**Street address**

Shahid Faghihi Hospital, Zand Avenue

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**Province**

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**Postal code**

7134846114

**Phone**

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**Email**

mmparvizi@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Younes Ghasemi

**Street address**

7th floor, Vice Chancellor of Research, Shiraz  
University of Medical Sciences, Zand Blvd., Shiraz,  
Iran

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**Phone**

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**Email**

vcrdep@sums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Mahdi Parvizi

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Traditional Medicine

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## Person responsible for scientific inquiries

**Contact**

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**Full name of responsible person**

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## Person responsible for updating data

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**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**

Demographic data and the results of the clinical trial

**When the data will become available and for how long**

6 month later

**To whom data/document is available**

Researchers

**Under which criteria data/document could be used**

After publication of the extracted article of the clinical trial

**From where data/document is obtainable**

Sending Email to the researchers

**What processes are involved for a request to access data/document**

ارسال درخواست از طریق ایمیل

**Comments**