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

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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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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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 scientific 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 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