Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Clinical evaluation of the brightening effect of Licorice (Glycyrrhiza glabra) and Cidr (Ziziphus spina-christi) mask on the skin in young people volunteering: The double-blind, randomized, placebo-controlled trial

Protocol summary

Study aim

Achieving a suitable formulation for the production of a facial mask containing Licorice and Cidr extract with a certain percentage and evaluating the effect of the product on brightening skin blemishes

Design

A controlled clinical trial with randomized, double-blind, parallel groups was performed on 48 patients. Random data function in mini-tab software is used for randomization.

Settings and conduct

This study is performed on people aged 18-50 years with any type of blemish such as pimples or sun spots referred to Imam Khomeini Hospital in Ahvaz. Randomization sequence of patients is performed using random numbers generated by Mini-tab software. Each person is given a tube containing a placebo or therapeutic mask, and a photograph of the face is taken monthly. The mask is applied twice a week for 2 months and is peeled off after 15 minutes.Three questionnaires related to the organoleptic properties and effect of the mask and psychological questions will be provided for monthly evaluation.

Participants/Inclusion and exclusion criteria

All women aged 18-50 years who have any hyper-pigmentation on the skin of their face and have signed a personal consent form, and are not pregnant, breastfeeding or using skin brightening products or oral contraceptives or sensitive to the product's ingredients.

Intervention groups

The main mask (medicine) is a peel off mask containing 12.6% Licorice extract and 5% Cidr extract. The placebo mask is a peel off mask that contains all the raw materials in the main mask except Licorice and Cidr extract, and in order to create a color and smell similar to the original mask, a combination of edible dyes and permitted essential oils has been added to it. .

Main outcome variables

Questionnaire of organoleptic properties of the mask; Questionnaire of the Brightening Effect on the Skin; Psychological Questionnaire; Photo of skin before and after applying the mask

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200128046288N6**
Registration date: **2022-06-25, 1401/04/04**
Registration timing: **retrospective**

Last update: **2022-06-25, 1401/04/04**
Update count: **0**

Registration date

2022-06-25, 1401/04/04

Registrant information

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Fereshteh Golfakhrabadi
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

2022-05-26, 1401/03/05

Expected recruitment end date

2022-06-05, 1401/03/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Clinical evaluation of the brightening effect of Licorice (Glycyrrhiza glabra) and Cidr (Ziziphus spina-christi) mask on the skin in young people volunteering: The double-blind, randomized, placebo-controlled trial

Public title
Formulation and clinical evaluation of the brightening effect of Licorice and Cidr mask on the skin
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All people who have anykind of hyper-pigmentation (acne spot- sunspot -...) with any degree. Willingness to participate in the study and signing the consent form
Exclusion criteria:
Pregnancy Breastfeeding Treatment with hormonal drugs and oral contraceptives Infection or skin disease at the study site Use of other lightening products in the last 6 months Inability to attend monthly visits
Age
From **18 years** old to **50 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization of patients is done using random numbers generated by the computer and Mini-tab software by Random data option. In this way, the people under study are numbered from 1 to 48 and then the software selects 24 random numbers from 1 to 24. These random numbers will be the number of people receiving tubes containing the mask, and 24 other patients receiving tubes containing placebo.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the placebo mask (which is completely similar to the original mask in terms of color and smell) and the main mask are coded and labeled A or B by a third party (who does not participate in the study). The subjects and the researcher only know the mask code and do not know the type of mask.The placebo mask is quite similar to the original mask in terms of color, smell and tube shape. Evaluation and analysis of data is done by the researcher.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences
Street address
Ahvaz Jundishapur University of Medical Sciences,, Golestan street
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61357-15794
Approval date
2022-05-11, 1401/02/21
Ethics committee reference number
IR.AJUMS.REC.1401.059

Health conditions studied

1

Description of health condition studied
Skin hyperpigmentation
ICD-10 code
L81.4
ICD-10 code description
Other melanin hyperpigmentation

Primary outcomes

1

Description
Degree of skin hyperpigmentation
Timepoint
Before the intervention, the first month and the second month after using the mask
Method of measurement
Self-assessment questionnaire on the effect of the mask on the skin, photos before and after using the product

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Peel off face mask of 12.6% Licorice extract and 5% Cidr extract will be made by the researchers of the present project and based on reliable sources. The mask is applied to the skin twice a week for 15 minutes and then washed off. This product was used for two months.
Category
Treatment - Drugs

2

Description
Control group: The placebo mask will be made by the researchers of the present project and based on reliable sources. The mask is applied to the skin twice a week for 15 minutes and then washed off. This product was used for two months.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahvaz Jundishapur University of Medical Sciences
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Fereshteh Golfakhrabadi
Position
Assistant professor
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Person responsible for scientific inquiries

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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
Deidentified individual participant data of study, study protocol, statistical analysis plan, informed consent form, clinical study report, analytic code, data dictionary will be shared after the study.
When the data will become available and for how long
The access time is up to 6 months after the results are published
To whom data/document is available
Six months after the publication of articles from this study, the data obtained will be made available to the applicant researchers for further analysis
Under which criteria data/document could be used
Six months after the publication of articles from this study, the data obtained will be made available to the applicant researchers for further analysis.
From where data/document is obtainable
Applicants can email the responsible author to receive the requested data golfakhrabadi@yahoo.com
What processes are involved for a request to access data/document
Applicants will have access to the data from the present study by emailing the responsible author for up to one month. golfakhrabadi@yahoo.com
Comments