

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Name

Fereshteh Golfakhrabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3373 8378

Email address

golfakhrabadi-f@ajums.ac.ir

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

City

Ahvaz

Province

Khuzestan

Postal code

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

Full name of responsible person

Freshteh Golfakhrabadi

Street address

Ahvaz Jundishapur University of Medical Sciences,,
Golestan street

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Phone

+98 61 3311 0000

Email

golfakhrabadi-f@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehdi Ahmadi Moghaddam

Street address

Ahvaz Jundishapur University of Medical Sciences,
Golestan street

City

Ahvaz

Province

Khouzestan

Postal code

6135733184

Phone

+98 61 6333 4142

Email

golfakhrabadi@yahoo.com

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

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Ahvaz Jundishapur University of Medical Sciences,
Golestan street

City

Ahvaz

Province

Khouzestan

Postal code

6135733184

Phone

+98 61 3373 8378

Email

golfakhrabadi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Fereshteh Golfakhrabadi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Ahvaz Jundishapur University of Medical Sciences,
Golestan street

City

Ahvaz

Province

Khuzestan

Postal code

6135733184

Phone

+98 61 3373 8378

Email

golfakhrabadi@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Fereshteh Golfakhrabadi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Ahvaz Jundishapur University of Medical Sciences,
Golestan street

City

Ahvaz

Province

Khuzestan

Postal code

6135733184

Phone

+98 61 3373 8378

Email

golfakhrabadi@yahoo.com

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