

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effectiveness of turmeric extract(Curcumin) in brightening lip color

Protocol summary

Study aim

Determining the effectiveness of turmeric extract in brightening lip color

Design

Clinical trial with control group, with parallel groups, one-way blind, randomized, phase 2-3 in 56 patients

Settings and conduct

This study is a interventional study that is performed on patients referred to the dermatology clinic of the Great Prophet Hospital with a complaint of dark lips. Individuals are randomly divided into two groups. One group is selected as a control and one group as an intervention group . The intervention (case)group is given a therapeutic product that is a curcumin-based lip balm and the control group is given a curcumin-free lip balm. Lip balm should be rubbed on the lips every 4 hours. All individuals in both groups are monitored monthly by lip imaging for 6 months and the results are recorded.

Participants are continuously monitored and in case of any side effects, the product is stopped.

Participants/Inclusion and exclusion criteria

Entry conditions: dark lips and completely healthy lip skin before the study No entry conditions:1. Presence of skin lesions or any sores or inflammation on the lips before the study 2. History of allergic reaction to curcumin

Intervention groups

The intervention group is given a therapeutic product that is a curcumin-based lip balm and the control group is given a curcumin-free lip balm. Lip balm should be rubbed on the lips every 4 hours.

Main outcome variables

Lip lightness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211111053038N1**

Registration date: **2022-06-22, 1401/04/01**

Registration timing: **retrospective**

Last update: **2022-06-22, 1401/04/01**

Update count: **0**

Registration date

2022-06-22, 1401/04/01

Registrant information

Name

Reyhaneh Pasandipour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3368 1176

Email address

reyhane.pasandipour@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-06-22, 1401/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of turmeric extract(Curcumin) in brightening lip color

Public title

Evaluation of the effectiveness of turmeric

extract(Curcumin) in brightening lip color

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

dark lips completely healthy lip skin before the study

Exclusion criteria:

Presence of skin lesions or any sores or inflammation on the lips before the study history of Allergic reaction to curcumin

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: 56

Randomization (investigator's opinion)

Randomized

Randomization description

The study is a simple one-way blind randomized clinical trial that 56 patients were randomly selected by simple sampling method among patients with dark lips who referred to the skin clinic of the Payambar Azam in Bandar Abbas after examining the inclusion and exclusion criteria. For the first step we prepare 56 similar small packages. In 28 packs we put a paper named A and in the other 28 packs we put papers named B, the patients don't know the content of packs. At the patient entrance let them to choose one pack randomly from all mixed 56 packs and give the chosen pack to doctor. The doctor will start the treatment based on the package name which is A(case group) or B(control group).

Blinding (investigator's opinion)

Single blinded

Blinding description

The participants of the control group are blind as receiving a therapeutic product without the substance evaluated in the study (curcumin). This group receives lip balm without curcumin

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Hormozgan University

of Medical Science

Street address

Hormozgan university of medical science , Chamran blvd

City

BandarAbbas

Province

Hormozgan

Postal code

7916613885

Approval date

2021-09-05, 1400/06/14

Ethics committee reference number

IR.HUMS.REC.1400.257

Health conditions studied

1

Description of health condition studied

Dark Lip Color

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The amount of lightening of lip color due to curcumin

Timepoint

Lip imaging at the beginning of the study and then every month for 6 months

Method of measurement

Mobile phone imaging and lip color comparison from the beginning to the end of the study

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: . The intervention group is given a therapeutic product that is a curcumin-based lip balm . For 6 months lip balm should be rubbed on the lips every 4 hours

Category

Treatment - Drugs

2

Description

Control group: control group is given curcumin-free lip balm. Lip balm should be rubbed on the lips every 4 hours.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Payambar Aazam hospital

Full name of responsible person

Sedigheh Tavakoli

Street address

Payambar Aazam hospital, infront of Farhangian alley

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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dr.tavakoli_s@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Bandare-abbas 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

Bandare-abbas University of Medical Sciences

Full name of responsible person

reyhaneh pasandipour

Position

medical student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for updating data

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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

No - There is not 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The main consequence of the study is that it can be shared without identifying individuals

When the data will become available and for how long

Access started 6 months after the end of the study

To whom data/document is available

Researchers working in academic and scientific institutions and the pharmaceutical industry

Under which criteria data/document could be used

Beauty researchers and pharmacists

From where data/document is obtainable

dr sedigheh tavakoli, Hormozgan university of medical science, bandarabbas 00987633333280

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

Contact Hormozgan university of medical science

Comments