Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison the therapeutic effects of liposomal tranexamic acid and Hydroquinone on melasma patients

Protocol summary

Summary

In this evaluation, 30 patients with melasma clinically diagnosed are entered to the study. This study is performed as double- blind randomized clinical trial by liposomal tranexamic acid on one side of the face and conventional Hydroquinone 4% on another side. Liposomal form will be prepared by fusion method. The size of these liposomes will be determined by the Particle Size Analyzer of Malvern device and surrounding percentage will be carried out by the direct method after separation of not encapsulated tranexamic acid by dialysis. Amount of tranexamic acid will be determined by spectrophotometry. Informed consent before entering the study will be obtained from all patients. In the first visit, severity of disease is recorded by Melasma Area and Severity Index (MASI). Then each patient two will be given two separate package containing form liposomal tranexamic acid and forms Hydroquinone 4% to the similar tubes with the numbers 1 and 2. The patients will be trained to use certain amount of either drug at nights. Sunscreen will be used daily every three hours for 12 weeks. Furthermore MASI will be recorded in each side of the face monthly and after one month of the last visit. All the patients are examined by one dermatologist during treatment course.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201403173862N10**
Registration date: **2014-04-15, 1393/01/26**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-04-15, 1393/01/26

Registrant information

Name
Farahzad Jababri Azad
Name of organization / entity
Mashahd University of Medical Scineces
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Nano Technology Research Center,Mashhad University of Medical Sciences

Expected recruitment start date

2011-08-03, 1390/05/12

Expected recruitment end date

2014-05-02, 1393/02/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the therapeutic effects of liposomal tranexamic acid and Hydroquinone on melasma patients

Public title

Comparison the therapeutic effects of liposomal tranexamic acid form and conventional form of Hydroquinone on melasma patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: clinically diagnosed melisma patients, age more than 18 years old. Exclusion criteria:

pregnancy and breast feeding, simultaneous hormonal disease, drug use including anti barbiturate drugs, recent hormonal and corticosteroids treatments, patients who treated by bleaching therapy on the last four months, patients underwent laser during the last six month, patients who don’t refer on follow up periods, any side effects which canceled the treatment.

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
This study is performed as double blind, as the patients and the physicians of disease severity are not alert about which therapeutic form will be used in each side of the face.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences

Street address
Central Building of Mashhad University of Medical Sciences (Ghorshi), daneshgah 16, Daneshgah Street

City
Mashhad

Postal code

Approval date
2010-09-23, 1389/07/01

Ethics committee reference number
910183

Health conditions studied

1

Description of health condition studied
Melasma

ICD-10 code
L81.1

ICD-10 code description
Melasma

Primary outcomes

1

Description
Improvement of pigmentation

Timepoint
Monthly untill the end of 12 weeks

Method of measurement
Melasma Area and Severity Index

Secondary outcomes

1

Description
Melasma severity

Timepoint
Comparison melasma severity in baseline and terminal of 3 months treatment course

Method of measurement
Melasma Area and Severity Index

Intervention groups

1

Description
Control group: hidroqinone cream 2%, one time/day on the lesion of one side of face

Category
Treatment - Drugs

2

Description
Intervention group: liposomal tranexamic acid cream 1 time/day on the lesion of one side of face

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ghaem hospital, Mashhad University of Medical Sciences

Full name of responsible person

Street address

City
Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research Council of Mashhad University of Medical Sciences

Full name of responsible person
Dr Mohsen Tafaghodi

Street address
Central Building of Mashhad University of Medical Sciences (Ghorshi), daneshgah 16, Daneshgah Street

City
Mashhad

Grant name

Grant code / Reference number

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

Title of funding source
Research Council of Mashhad University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Asma Jabari

Position
Medical student

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Dr Mahnaz banihashemi, Dr Mahmoud Reza Jafari, Dr Naghmeh Zabolinejad

Position
Associate professor of dermatology, Professor of Pharmasutics, Assistant professor of dermatology

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Name of organization / entity
Leishmaniasis Research Center

Full name of responsible person
Akram Momenzadeh

Position

Other areas of specialty/work

Street address

City

Postal code

Phone

Fax

Email

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty