

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 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

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1843 6626

Email address

banihashemim@mums.ac.ir

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 until 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: hidroquinone 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**Street address**

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Person responsible for scientific

inquiries

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Mashhad University of Medical Sciences

Full name of responsible person

Dr Mahnaz banhashemi, Dr Mahmoud Reza Jafari, Dr Naghmeh Zabolnejad

Position

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

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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