

# 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

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##### 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

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## Person responsible for scientific

## inquiries

**Contact****Name of organization / entity**

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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## 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*