Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Comparision of efficacy of 4% hydroquinone alone and combined with Plasma rich in growth factor (PRGF) in the treatment of melasma

Protocol summary

Study aim
Comparison of combination of hydroquinone 4% and plasma rich in growth factor (PRGF) with hydroquinone 4% alone in the treatment of melasma patients

Design
the study is a double-blind,randomized clinical trial with control group.

Settings and conduct
this is a randomized double-blind clinical trial study.20 female patients with minimum age of 18 years old and maximum age of 50 years old with diagnosed melasma attending dermatology clinic Afzalipour hospital in Kerman enroll the study.patients are allocated to 2 groups (intervention and control).intervention group will recieve combination of hydroquinone 4% and plasma rich in growth factors(PRGF) and control group will recieve hydroquinone 4% as monotherapy.

Participants/Inclusion and exclusion criteria
inclusion criteria : female patients with diagnosed melasma with minimum age 18 years old and maximum age 50 years old exclusion criteria : pregnancy, lactation, ocp use, history of allergy to the components of the formulation.

Intervention groups
The intervention group consisted of 4% hydroquinone made by Shafa company (locally and once a day for 3 months) and injection of growth factor-rich plasma (PRGF) as an injection once every two weeks for six sessions on one side of the face and group Controlling the other side of the face with 4% hydroquinone treatment by Shafa company as monotherapy (locally once a day for up to 3 months)

Main outcome variables
Melasma severity, patients satisfaction, physician satisfaction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221016056188N1**
Registration date: **2022-11-02, 1401/08/11**
Registration timing: **prospective**

Last update: **2022-11-02, 1401/08/11**
Update count: **0**

Registration date
2022-11-02, 1401/08/11

Registrant information

Name
Mahboobe Karimi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-11-10, 1401/08/19

Expected recruitment end date
2023-03-10, 1401/12/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparision of efficacy of 4% hydroquinone alone and combined with Plasma rich in growth factor (PRGF) in the treatment of melasma

Public title
evaluating effectivness of Plasma rich in growth factor (PRGF) in the treatment of melasma
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
female patients with minimum age 18 years old and maximum age 50 years old patients with diagnosed melasma
Exclusion criteria:
pregnancy lactation OCPusers history of allergy to the components of formulation
Age
From **18 years** old to **50 years** old
Gender
Female

Phase
2-3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **20**
More than 1 sample in each individual
Number of samples in each individual: **2**
1- Combined treatment of hydroquinone 4% and plasma rich in growth factor (PRGF) on one side of the face 2- Hydroquinone 4% treatment as monotherapy on the other side of the face
Randomization (investigator's opinion)
Randomized
Randomization description
For every patient, a simple randomization method (flipping a coin) is used to determine which side of the face will receive the combined treatment and thus the other side of face receiving the hydroquinone 4% as monotherapy.
Blinding (investigator's opinion)
Double blinded
Blinding description
Our study was a double-blind manner, which means that the type of treatment was unknown for outcom assessor and analyzor.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kerman University of Medical Scinces
Street address
Ebn Sina Aven, Tahmasb Abad Blvd
City
Kerman
Province
Kerman
Postal code
7616913555
Approval date
2022-10-31, 1401/08/09
Ethics committee reference number
IR.KMU.AH.REC.1401.161

Health conditions studied

1

Description of health condition studied
melasma
ICD-10 code
L81.4
ICD-10 code description
other melanin hyperpigmentation

Primary outcomes

1

Description
Melasma severity
Timepoint
at the begining of the study (before intervention) and 4,8 , 12 weeks after intervention
Method of measurement
According to Melasma Area and Severity index score

2

Description
Patients satisfaction
Timepoint
4, 8, 12 weeks after begining of the intervention
Method of measurement
Using Patients Global Assessment score

3

Description
Physician satisfaction
Timepoint
4, 8, 12 weeks after begining of the intervention
Method of measurement
Using Physician Global Assessment score

Secondary outcomes

1

Description
Erythema

Timepoint
At the begining of the study (before intervention) and 4,8,12 weeks after begining of the intervention
Method of measurement
By physical examination and classification of the complications severity into mild, moderate and severe

2

Description
swelling
Timepoint
4,8,12 weeks after begining of the intervention
Method of measurement
By physical examination and classification of the complications severity into mild, moderate and severe

3

Description
Burning
Timepoint
4,8,12 weeks after begining of the intervention
Method of measurement
According to the expression of the patient's feelings and classification of the complications severity into mild, moderate and severe

4

Description
dryness
Timepoint
At the begining of the study (before intervention) and 4,8,12 weeks after begining of the intervention
Method of measurement
By physical examination and classification of the complications severity into mild, moderate and severe

Intervention groups

1

Description
Intervention group: combination 4% hydroquinone (Shafa-Iran manufacturing company) locally once a day and injection of plasma rich in growth factor (PRGF) by injection once every two weeks for 12 weeks.
Category
Treatment - Drugs

2

Description
Control group: : 4% hydroquinone (Shafa-Iran manufacturing company) locally once a day in other side of face as monotherapy for 12 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Afzalipour hospital
Full name of responsible person
Rezvan Amiri
Street address
Afzalipour hospital,Imam highway,Kerman
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Ali Reza Farsinejad
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman 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
Kerman University of Medical Sciences

Full name of responsible person
Rezvan Amiri

Position
Assistant of professor of dermatology

Latest degree
Specialist

Other areas of specialty/work
Dermatology

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Position
Assistant professor of dermatology

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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
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available