Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Comparison of the therapeutic response of both PRP and 15% AHA versus 15% AHA alone in patients with facial wrinkles

Protocol summary

Study aim
Comparison of the therapeutic response of both PRP and 15% AHA versus 15% AHA alone in patients with facial wrinkles.

Design
Randomized clinical trial without blinding, phase 3, with cross-groups on 60 patients

Settings and conduct
This study will be performed in the dermatology clinic of Sina Hospital in Tabriz. There will be no blinding.

Participants/Inclusion and exclusion criteria
inclusion criteria were age between 18 to 45 years and satisfaction to participate in the study. Exclusion criteria were platelet disorder or blood clots, chronic liver disease, history of drug treatment with bleeding or clotting mechanisms, pregnancy and cosmetic treatments in the past 6 months.

Intervention groups
Intervention group: Patients will receive 15% alpha-hydroxy acid overnight topically with platelet-rich plasma injection every two months for 6 months. Control group: Patients will receive 15% alpha-hydroxy acid topically overnight for 6 months.

Main outcome variables
Intensity of wrinkles, degree of tissue healing and homogeneity of facial skin, patient satisfaction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140705018373N5**
Registration date: **2020-11-11, 1399/08/21**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-11, 1399/08/21**
Update count: **0**

Registration date
2020-11-11, 1399/08/21

Registrant information

Name
Mohamad Reza Ranjkesh

Name of organization / entity
Tabriz University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-09-22, 1399/07/01

Expected recruitment end date
2020-11-21, 1399/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the therapeutic response of both PRP and 15% AHA versus 15% AHA alone in patients with facial wrinkles

Public title
Effect of both PRP and 15% AHA versus 15% AHA alone on facial wrinkles

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 to 45 years Satisfaction to participate in the study

Exclusion criteria:

Platelet disorder or blood clots Chronic liver disease Autoimmune diseases History of drug treatment with bleeding or clotting mechanisms, Having cosmetic treatments in the past 6 months Pregnancy

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization done using the file number of patients by site www.random.org and the Gaussian order. According to the study method, all patients will receive 15% AHA treatment and will be added in a PRP group. The cost of 15% AHA is part of the treatment routine, but the cost of PRP will be done in one group from the place of study costs. Therefore, additional costs are not borne by patients.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Sina hospital, between Hafez and Shahid-Montazeri square, Azadi street

City

Tabriz

Province

East Azarbaijan

Postal code

5163639888

Approval date

2020-09-28, 1399/07/07

Ethics committee reference number

IR.TBZMED.REC.1399.698

Health conditions studied

1

Description of health condition studied

Facial wrinkles

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Facial wrinkles severity

Timepoint

Initiation of the study, 1, 3 and 6 months after the intervention

Method of measurement

Wrinkle Severity Rating Scale

2

Description

Degree of tissue healing and homogeneity of facial skin

Timepoint

Initiation of the study, 1, 3 and 6 months after the intervention

Method of measurement

Skin Homogeneity and Texture Scale

3

Description

Patient satisfaction

Timepoint

6 months after the intervention

Method of measurement

Asking from patients on a scale of 1 to 5 range from very dissatisfied to very satisfied

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients will receive 15% alpha-hydroxy acid overnight topically with platelet-rich plasma injection every two months for 6 months.

Category

Treatment - Drugs

2

Description

Control group: Patients will receive 15% alpha-hydroxy acid topically overnight for 6 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Sina Hospital

Full name of responsible person
Dr. Mohammadreza Ranjkesh

Street address
Sina hospital, Azadi Ave., Tabriz town, East Azarbyjan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Mohammad Samiee

Street address
Floor 3, Unit 2, Tabriz university of medical sciences, Golgasht street

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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
Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Mohammadreza Ranjkesh

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Dermatology

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Study data is categorized and coded with no identifiable individuals.
When the data will become available and for how long
Access to study data after publication of the result is available in the journal.
To whom data/document is available
Anyone interested in using the data can access the study data.
Under which criteria data/document could be used
Study data can be used for comparison with other results.
From where data/document is obtainable
Refer to the study's scientific or public accountability person for data.
What processes are involved for a request to access data/document
The request will be sent by email to person responsible for scientific or public inquiries.
Comments