Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jul 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)
Phone
+98 914 116 5061
Email address
ranjkeshm@tbzmed.ac.ir

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
City
Tabriz
Province
East Azarbaijan
Postal code
5163639888
Phone
+98 41 3549 8236
Email
ranjkeshm@tbzmed.ac.ir

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
City
Tabriz
Province
East Azarbaijan
Postal code
5163639888
Phone
+98 41 3335 7310
Email
samiei.moh@gmail.com
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
Street address
Sina hospital, Azadi Ave., Tabriz town, East Azarbyjan
City
Tabriz
Province
East Azarbaijan
Postal code
5163639888
Phone
+98 41 3549 8236
Email
ranjkeshm@tbzmed.ac.ir

Person responsible for scientific 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
Street address
Sina hospital, Azadi Ave., Tabriz town, East Azarbyjan
City
Tabriz
Province
East Azarbaijan
Postal code
5163639888
Phone
+98 41 3549 8236
Email
ranjkeshm@tbzmed.ac.ir

Person responsible for updating data

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

Street address

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

City

Tabriz

Province

East Azarbaijan

Postal code

5163639888

Phone

+98 41 3549 8236

Email

ranjkeshm@tbzmed.ac.ir

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