

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Evaluation of Effect of Local Injection of Umbilical Cord Blood Derived Serum versus Local Injection of Platelet Rich Plasma in the Treatment of Striae Distensae(A randomized controlled intervention study)

Protocol summary

Study aim

Investigating the effect of local injection of serum derived from umbilical cord blood compared to local injection of autologous platelet-rich plasma (PRP) in the treatment of stretch marks

Design

A clinical trial with a control group, with 3 groups of 10 people, double-blind, randomized, phase 2 on 30 patients. A simple randomization method was used for randomization.

Settings and conduct

One-to-one intradermal injection with a volume of 1ml in the arm area in Skin and Hair Research Center, Tehran University of Medical Sciences

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age 50-18 years; Full consent of the patient to participate in the project; Having striae of type alba (with all three grades from mild to severe);
Exclusion criteria: Inflammatory acne; Active herpes labialis; Infection in the treatment area; keloid; malignancy; Pregnancy; Breastfeeding; Immunosuppression; Use of local and systemic steroids; Systemic diseases (Such as high blood pressure; Diabetes; Heart disease; Cancer; Kidney and Liver)

Intervention groups

Patients are divided into 3 groups. The first group was treated with cord blood serum with a concentration of 2%, the second group with cord blood serum with a concentration of 5% and the third group with cord blood serum with a concentration of 10%, in groups 1, 2 and 3 patients for 4 sessions with intervals of 2 weeks to The injection is done in the right arm of the areas with stretch marks and the PRP injection is done in the left arm with stretch marks. The injection of each of the study groups will be done in the next dose after 4 weeks if there are no side effects in the first dose.

Main outcome variables

Variable name; Tested groups; Type of treatment; Complications of treatment; Recovery rate; recovery time; sex; Age; Patient satisfaction; The amount of skin collagen; Thickness of epidermis and dermis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221130056672N2**

Registration date: **2023-11-25, 1402/09/04**

Registration timing: **prospective**

Last update: **2023-11-25, 1402/09/04**

Update count: **0**

Registration date

2023-11-25, 1402/09/04

Registrant information

Name

EHSAN Taghiabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2665 7541

Email address

etaghiaadi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2024-02-09, 1402/11/20

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of Effect of Local Injection of Umbilical Cord Blood Derived Serum versus Local Injection of Platelet Rich Plasma in the Treatment of Striae Distensae(A randomized controlled intervention study)

Public title
Effect of Local Injection of Umbilical Cord Blood Derived Serum versus Local Injection of Platelet Rich Plasma in the Treatment of Striae Distensae

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 and 50 years Full satisfaction of the participant in the plan Has striae alba (with all three degrees of mild, moderate, severe)
Exclusion criteria:
Inflammatory acne Active herpes labialis Local infections in the treatment area Prone to keloid Malignancy Pregnancy Breastfeeding Use of drugs that can affect bleeding or clotting mechanism Immunosuppression Use of local and systemic steroids Disease systemic diseases (such as high blood pressure ,Diabetes ,heart, kidney and liver diseases) The use of exfoliators 4 weeks before treatment In places where botulinum injection has been done, should not be done due to the possibility of microneedle toxin release.

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
1-2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Using the simple randomization method, the patients who visit Dr. Nilfroshzadeh's skin clinic are divided into 3 groups, so that one envelope is randomly selected for each patient from the number of 30 sealed envelopes. will be Inside each envelope is the letter A, B or C. Group A patients will be treated with cord blood serum with a concentration of 2%, group B will be treated with cord blood serum with a concentration of 5% and group C patients will be treated with cord blood serum with a concentration of 10%.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study,the participant researcher,doctor and evaluating doctor will be unaware of the type of treatment until the end of the study.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences
Street address
Deputy Research and Technology Office, 6th Floor , Central Organization of Tehran Universit of Medical Sciences Qods St, Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
1416613675
Approval date
2023-10-30, 1402/08/08
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1402.404

Health conditions studied

1

Description of health condition studied
Striae Distensae
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Epidermis and dermis thickness
Timepoint
Before the start of the intervention and two months after the end of the treatment period (Four months after the start of the treatment)
Method of measurement
Skin Scanner

2

Description

The amount of collagen formation

Timepoint
Before the start of the intervention and two months after the end of the treatment period (Four months after the start of the treatment)

Method of measurement
Visoface

Secondary outcomes

1

Description

Safety

Timepoint

At the beginning of the intervention, at each re-visit session and two months after the end of the treatment period (four months after the start of the treatment)

Method of measurement

Patient history

2

Description

Effectiveness

Timepoint

At the beginning of the intervention, at each re-visit session and two months after the end of the treatment period (four months after the start of the treatment)

Method of measurement

Patient satisfaction

Intervention groups

1

Description

Intervention group: Treated Local Injection of Umbilical Cord Blood Derived Serum

Category

Treatment - Other

2

Description

Control group: Treated Local Injection of Platelet Rich Plasma

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Skin and Stem Cell Research Center, Tehran
University of Medical Sciences

Full name of responsible person

Mohammad Ali Nilfrooshzadeh

Street address

No.4 Maryam Dead End South Kamraniyeh, Andarzgo

Blv, Tehran Province, Tehran

City
Tehran

Province
Tehran

Postal code
1937957511

Phone
+98 21 2665 7541

Email
etaghiajadi@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Nilfrooshzadeh

Street address

Research and Technology Deputy, 6th floor , Quds St,
Tehran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1937957511

Phone

+98 21 2665 7438

Email

etaghiajadi@sina.tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Ehsan Taghiabadi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Applied cell sciences

Street address

No.4, 4th floor, Maryam dead end. South Kamraniyeh

City

Tehran

Province

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Postal code

1937957511

Phone

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Email

etaghlabadi@sina.tums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Ehsan Taghiabadi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Biotechnology

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Person responsible for updating data**Contact****Name of organization / entity**

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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

Yes - There is 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

All data can be shared after de-identifying individuals.

When the data will become available and for how long

Six months after the publication and printing of the article

To whom data/document is available

Academic researchers and experts

Under which criteria data/document could be used

In order to analyze the results of the study outcomes

From where data/document is obtainable

etaghlabadi@sina.tums.ac.ir

What processes are involved for a request to access data/document

It can be submitted after review by the Research Council of the Skin and Stem Cell Research Center of Tehran University of Medical Sciences, which usually takes 2 to 3 months.

Comments