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)

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

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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

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
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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
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
etaghiabadi@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