

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Evaluation and Comparison of the Efficacy and Safety of Platelet-Rich Fibrin, 5-Fluorouracil, and Their Combination in the Treatment of Burn-Induced Keloids in Patients Treated with Intense Pulsed Light, Fractional CO₂ Laser, or Their Combination

Protocol summary

Study aim

Comparing Efficacy and Safety of Platelet-Rich Fibrin, 5-Fluorouracil, and Their Combination for Burn Keloids in Laser Patients

Design

A phase II, three-arm, parallel-group, double-blind, randomized clinical trial conducted on 17 patients. Randomization was performed using the RAND function in Microsoft Excel.

Settings and conduct

A phase II, randomized, double-blind, three-arm trial in patients with at least three comparable burn-induced keloids. Following laser/IPL therapy, each lesion is randomly assigned to receive intralesional PRF, 5-FU, or their combination over three monthly sessions. Patients and outcome assessors are blinded using identical syringes and concealed codes.

Participants/Inclusion and exclusion criteria

Aged 18 years or older. Patients with a confirmed diagnosis of at least three (3) burn-induced keloid lesions. Currently undergoing or scheduled to undergo treatment with Intense Pulsed Light (IPL) therapy, fractional CO₂ laser therapy, or a combination of both modalities. Total keloid area of at least 10 × 10 cm² or the presence of a single lesion with a minimum length of 10 cm. Not pregnant or lactating. No underlying medical conditions known to impair wound or scar healing. Demonstrated commitment to adhere to all study interventions and attend all scheduled treatment sessions.

Intervention groups

Platelet-Rich Fibrin: Autologous intralesional injection, 0.5-1 mL per cm² until blanching. 5-Fluorouracil: Intralesional injection (50 mL solution) in three monthly sessions until blanching. Combination therapy: Concurrent injection of Platelet-Rich Fibrin and 5-

Fluorouracil into a single lesion according to the above protocols.

Main outcome variables

Vascularity : Pigmentation: Height/Elevation : Pliability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150529022468N7**

Registration date: **2026-02-05, 1404/11/16**

Registration timing: **prospective**

Last update: **2026-02-05, 1404/11/16**

Update count: **0**

Registration date

2026-02-05, 1404/11/16

Registrant information

Name

Mohammadreza Ghassemi

Name of organization / entity

Iran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-03-11, 1404/12/20

Expected recruitment end date

2026-07-23, 1405/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation and Comparison of the Efficacy and Safety of Platelet-Rich Fibrin, 5-Fluorouracil, and Their Combination in the Treatment of Burn-Induced Keloids in Patients Treated with Intense Pulsed Light, Fractional CO₂ Laser, or Their Combination

Public title

Efficacy and Safety of Platelet-Rich Fibrin, 5-Fluorouracil, and Their Combination in the Treatment of Burn-Induced Keloids

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients aged over 18 years Patients with a confirmed diagnosis of burn-induced keloid(s), with a minimum of 3 lesions Undergoing treatment with IPL laser, CO₂ laser, or a combination of both. Having a total affected area of at least 10 × 10 cm² or a lesion with a minimum length of 10 cm. Not pregnant or lactating. Free from underlying medical conditions that could impair scar healing, such as diabetes mellitus or immunosuppression. Patient compliance with all therapeutic interventions and attendance at every treatment session.

Exclusion criteria:

Occurrence of pregnancy during the treatment or follow-up period. Development of hypersensitivity or any adverse reaction to any of the treatment interventions that would preclude continuation of therapy Diagnosis of malignancy or a systemic disease during the treatment or follow-up period. Onset of bacterial or viral skin infections during the treatment or follow-up period.

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **17**

Randomization (investigator's opinion)

Randomized

Randomization description

For the random allocation of treatments to the three keloid lesions in each patient, a block randomization method with appropriate allocation concealment will be employed. For this purpose, all possible sequences (6 orders) for arranging the three studied

treatments—namely PRP, 5-FU, and the combined method—will be prepared. These sequences will be randomly organized into blocks, and each will be placed in separate, sealed envelopes. In each patient, the three lesions will be identified and labeled according to their anatomical position (upper, middle, and lower). At the time of intervention, an envelope will be randomly opened for the patient, and the treatment sequence inside will determine which treatment is allocated to which lesion: the first element of the sequence to the upper lesion, the second to the middle lesion, and the third to the lower lesion. For example, if the selected sequence is "BCA," the upper lesion will receive 5-FU, the middle lesion will receive the combined therapy, and the lower lesion will receive PRP. This process, along with the use of sealed envelopes, ensures statistically balanced allocation and prevents any bias by concealing the sequences until the moment of allocation.

Blinding (investigator's opinion)

Double blinded

Blinding description

Given that the injection syringes will be identical in appearance and the contents of the syringes will be indistinguishable, patients will be blinded to the type of intervention they receive. Furthermore, each intervention will be labeled with a specific code, and the outcome assessor will be blinded to the intervention type when evaluating treatment results.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Iran University of Medical Sciences

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Iran University of Medical Sciences Hemmat Highway, Adjacent to Milad Tower Tehran

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۱۴۳۹۶۱۴۵۳۵

Approval date

2025-10-19, 1404/07/27

Ethics committee reference number

IR.IUMS.FMD.REC.1404.479

Health conditions studied

1

Description of health condition studied

Keloid treatment

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Vascularity

Timepoint

At baseline (before intervention) and at 1, 2, and 3 months after the initiation of treatment.

Method of measurement

Vancouver scar scale

2

Description

Pigmentation

Timepoint

At baseline (before intervention) and at 1, 2, and 3 months after the initiation of treatment.

Method of measurement

Vancouver scar scale

3

Description

Height/Elevation of the Lesion

Timepoint

At baseline (before intervention) and at 1, 2, and 3 months after the initiation of treatment.

Method of measurement

Vancouver scar scale

4

Description

Pliability of the lesion

Timepoint

At baseline (before intervention) and at 1, 2, and 3 months after the initiation of treatment.

Method of measurement

Vancouver scar scale

Secondary outcomes

1

Description

Adverse Events

Timepoint

At 1, 2, and 3 months after the initiation of treatment

Method of measurement

Checklist

2

Description

Treatment tolerability

Timepoint

At 1, 2, and 3 months after the initiation of treatment

Method of measurement

Checklist

3

Description

Treatment satisfaction

Timepoint

At 1, 2, and 3 months after the initiation of treatment

Method of measurement

Checklist

Intervention groups

1

Description

Intervention group: Platelet-Rich Fibrin : For this procedure, approximately 10-20 mL of venous blood is drawn from the patient and centrifuged in special tubes without anticoagulant at 3000 RPM for 10-14 minutes. Following centrifugation, the middle layer (PRF gel), which contains platelets, leukocytes, and growth factors, is separated and prepared as an injectable fibrin matrix. The injection volume will be 0.5-1 mL per square centimeter of the keloid surface area. The injection will be performed using an intralesional technique with a 27-30 gauge needle, at multiple points spaced 1 cm apart, until mild blanching is achieved. This protocol will remain consistent across all treatment sessions.

Category

Treatment - Drugs

2

Description

Intervention group: 5-Fluorouracil : Treatment of burn-induced keloids with 5-fluorouracil is administered via intralesional injection over three sessions at one-month intervals. To implement the protocol, a 50 mg/mL solution of 5-FU is prepared and, if needed for patient comfort, diluted with 1% lidocaine at a ratio of 2:8 (2 parts 5-FU to 8 parts lidocaine). Injection is performed using a fine-gauge needle (27-30 gauge) via the intralesional technique at multiple points spaced 0.5 to 1 cm apart. The needle is advanced to the mid-dermal layer, and the agent is injected slowly until localized blanching of the keloid is observed. The first treatment session is delivered on day 0 (baseline), the second on day 30 (± 3 days), and the third on day 60 (± 3 days).

Category

Treatment - Drugs

3

Description

Intervention group: Combination Therapy: In the

combined method, a combination of the two studied interventions will be applied to the lesion. The volume and dosage used will be identical to those administered in the other treatment arms.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Motahari Educational and Medical Center

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Mohammadreza Ghassemi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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

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Position

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Latest degree

Specialist

Other areas of specialty/work

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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)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available