Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 CO_2 laser therapy, or a combination of both modalities. Total keloid area of at least 10 × 10 cm^2 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 cm^2 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

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Name of organization / entity
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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, CO_2 laser, or a combination of both. Having a total affected area of at least 10 × 10 cm^2 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
Street address
Iran University of Medical Sciences Hemmat Highway, Adjacent to Milad Tower Tehran
City
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Province
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Postal code
۱۴۴۹۶۱۴۵۳۵
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
Keliod 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
Mohammadreza Ghassemi

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Motahari Educational and Medical Center , Rashid Yasami Street, Mirdamad District, Valiasr Street,Tehran

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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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Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
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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