ISRCTN65774128 https://doi.org/10.1186/ISRCTN65774128

Study of jaw function after injection of platelet-rich fibrin into the jaw joint in people with temporomandibular disorders

Submission date 14/08/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 14/08/2026	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 14/08/2026	**Condition category** Digestive System	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Temporomandibular disorders are conditions affecting the jaw joints and the muscles involved in jaw movement. They may cause pain, restricted mouth opening, and difficulties with normal jaw function. This study investigated changes in pain, jaw movement and jaw function following intra-articular injection of autologous injectable platelet-rich fibrin (i-PRF) in adults with temporomandibular disorders.

Who can participate?
Patients aged 18–65 years with a temporomandibular disorder

What does the study involve?
Participants received two intra-articular injections of autologous injectable platelet-rich fibrin into the affected temporomandibular joint. The second injection was given 1 week after the first. The i-PRF was prepared from the participant's own venous blood immediately before administration.
Participants were assessed before treatment and during follow-up. Jaw functional limitation, pain intensity and maximum mouth opening were assessed at predefined time points, including 1 week after the first injection, 1 week after the second injection, and subsequent follow-up assessments at 1 month and 3 months after treatment.

What are the possible benefits and risks of participating?
Participants may or may not experience an improvement in jaw pain, mouth opening or jaw function following treatment. As with intra-articular injection procedures, possible risks include temporary pain or discomfort, swelling, bleeding, bruising, infection, or other local reactions. Because the treatment uses the participant's own blood-derived material, the risk of an immune reaction to the injected material is expected to be low.

Where is the study run from?
University Clinical Center of Kosovo (Kosovo)

When is the study starting and how long is it expected to run for?
April 2024 to September 2026

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
1. Dr Venera Bimbashi, vbimbashi@gmail.com
2. Dr Besim Hajdari, besim.hajdari@uni-pr.edu

Contact information

Type(s)
Scientific, Principal investigator, Public

Contact name
Dr Besim Hajdari

Contact details
University Clinical Center of Kosovo, Hospital Area
Prishtina
Kosovo
10000
+383 (0)44272787
besim.hajdari@uni-pr.edu

Additional identifiers

Study information

Scientific Title
Functional outcomes following intra-articular injectable platelet-rich fibrin injection in patients with temporomandibular disorders: a prospective single-arm interventional clinical study

Acronym
iPRF-TMD

Study objectives
Temporomandibular disorders are common conditions affecting the temporomandibular joint and associated structures and may cause pain, restricted jaw movement, and impaired mandibular function. Injectable platelet-rich fibrin is an autologous blood-derived biomaterial containing platelets and leukocytes and has been proposed as a biological treatment to support tissue healing and reduce symptoms associated with temporomandibular disorders.

The primary aim of the study was to evaluate changes in functional outcomes following intra-articular injectable platelet-rich fibrin treatment in patients with temporomandibular disorders. The study was not prospectively registered because, at the time of study initiation and participant enrollment, the investigators were unaware that prospective registration was required for this type of interventional clinical study. The study is being registered retrospectively to provide transparent public documentation of the study design and conduct.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/05/2023, Ethics committee of the Faculty of Medicine, University of Prishtina (Faculty of Medicine University of Prishtina “Hasan Prishtina” Bulevardi i Dëshmorëve, p.n., Prishtina, 10000, Kosovo; +383 (0)38 512 221; mjekesia@uni-pr.ed), ref: 3698/2023

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Temporomandibular disorders (TMD), including temporomandibular joint dysfunction and associated limitations in jaw function

Interventions
Participants received intra-articular injections of autologous injectable platelet-rich fibrin (i-PRF) for the treatment of temporomandibular disorders. For preparation of i-PRF, 13 ml of peripheral venous blood was collected from each participant and processed using a Duo Quattro PRF centrifuge at 700 rpm for 3 minutes. The resulting injectable platelet-rich fibrin was prepared immediately before administration.

The i-PRF was administered intra-articularly into the affected temporomandibular joint using a sterile 30-gauge needle. Each participant received two intra-articular injections, with the second injection administered 1 week after the first. The injection procedure was performed under aseptic conditions following disinfection of the injection site with povidone-iodine (Betadine).

Intervention Type
Biological/Vaccine

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Autologous injectable platelet-rich fibrin (i-PRF)

Primary outcome(s)
1. Temporomandibular disorder-related pain intensity measured using the study's predefined pain assessment scale at baseline (before the first i-PRF injection), 1 week after the first injection, 1 week after the second injection, 1 month after treatment, and 3 months after treatment

2. Maximum mouth opening (MMO) measured using a digital stainless-steel vernier caliper (TITAN) at baseline (before the first i-PRF injection), 1 week after the first injection, 1 week after the second injection, 1 month after treatment, and 3 months after treatment

3. Jaw functional limitation measured using the Jaw Functional Limitation Scale-20 (JFLS-20) total score at baseline (before the first i-PRF injection), 1 week after the first injection, 1 week after the second injection, 1 month after treatment, and 3 months after treatment

Key secondary outcome(s)

Completion date
11/09/2026

Eligibility

Key inclusion criteria
1. Adult patients with a clinical diagnosis of temporomandibular disorders (TMD) based on the Diagnostic Criteria for Temporomandibular Disorders (DC/TMD)
2. Presented with pain associated with disco-condylar incoordination (disc displacement with or without locking, clicking, or crepitation) and persistent temporomandibular joint (TMJ) and/or masticatory muscle pain refractory to at least 4 weeks of conservative management, including analgesics, occlusal splint therapy, or physiotherapy
3. All participants were required to be willing to undergo i-PRF treatment and adhere to the follow-up protocol

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment

Key exclusion criteria
1. Patients diagnosed with TMJ osteoarthritis, articular disc perforation, growth disorder syndromes, infectious arthritis, or bilateral arthralgia
2. Pregnant
3. History of previous TMJ surgical interventions
4. Presented with systemic conditions that could impair soft or hard tissue healing
5. Patients with contraindications to platelet-rich fibrin therapy, such as fibrin deficiency, platelet function disorders, or current anticoagulant therapy

Date of first enrolment
15/04/2024

Date of final enrolment
11/06/2026

Locations

Countries of recruitment
Kosovo

Study participating centre
University Clinical Center of Kosovo
Department of Maxillofacial Surgery
Hospital Area
Prishtina
Kosovo
10000

Sponsor information

Organisation
University Clinical Center of Kosovo

ROR
https://ror.org/005tw0h26

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available