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Histological evaluation of intraarticular hypertonic dextrose in knee osteoarthritis

Submission date	Recruitment status	[ ] Prospectively registered
23/11/2026	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
25/11/2026	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
25/11/2026	Musculoskeletal Diseases	[X] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Principal investigator, Scientific, Public

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Study information

Scientific Title
Evaluation of the effects of intraarticular hypertonic-dextrose injection in knee osteoarthritis using histological techniques

Acronym

EEIHDIKOUHT

Study objectives
To evaluate the biological response of Prolotherapy on osteoarthritic knees.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/02/2018, Gaziosmanpaşa University Faculty of Medicine Dean's Office - Clinical Research Ethics Committee (Gaziosmanpaşa University Faculty of Medicine Dean's Office, Tokat, 60200, Türkiye; +90 3562521616; gensek@gop.edu.tr), ref: 18-KAEK-025

Primary study design
Observational

Secondary study design
Prospective comparative histological study

Study type(s)

Health condition(s) or problem(s) studied
Osteoarthritic knees

Interventions
Patients in the Prolo+ group received up to six sessions of ultrasound-guided intra-articular and peri-articular hypertonic dextrose injections (4 mL of 25% dextrose intra-articularly + 8 mL of 15% dextrose with lidocaine to peri-articular structures). Patients in the Prolo– group received only conservative treatment for at least three months.
Bone and cartilage specimens (3 mm × 10 mm × 3 mm) were obtained from the medial femoral and tibial condyles during total knee arthroplasty in both groups and processed for histomorphometric, histochemical (Safranin O–fast green, H&E) and immunohistochemical analyses (PDGF, TGF-β1, TGF-β3, BMP-2, MMP-2).

Intervention Type
Other

Primary outcome(s)
1. Histomorphometric findings measured using average tissue amount in a unit area on the part of bone tissue facing the joint surface, assessed by histological examination and compared using the Mann-Whitney U test at a single time point during the study

2. Immunohistochemical expression of PDGF, TGF, BMP2 and MMP2 measured using immunohistochemical staining, H-score conversion and statistical comparison using the independent samples t-test at a single time point during the study

Key secondary outcome(s)

Completion date
24/06/2018

Eligibility

Key inclusion criteria
Patients who had chronic knee osteoarthritis

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
40 Years

Upper age limit
70 Years

Sex
All

Total final enrolment
95

Key exclusion criteria
1. Diabetes mellitus
2. Rheumatic arthritis
3. Another systemic inflammatory problems, osteomyelitis, or chronic infection or active infection
4. Corticosteroid injections or injections of any other regenerative solutions (platelet-rich plasma, hyaluronic acid, etc.)

Date of first enrolment
02/03/2018

Date of final enrolment
19/04/2018

Locations

Countries of recruitment
Türkiye

Sponsor information

Organisation
Department of Hystology, Tokat Gaziosmanpaşa University

Funder(s)

Funder type

Funder Name
Department of Hystology, Tokat Gaziosmanpaşa University

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available