

Study Title

Effect of Arthroscopic Microfracture Combined with Stromal Vascular Fraction Therapy on Clinical and Radiological Outcomes in Gonarthrosis: A Prospective Randomized Controlled Trial

NCT Number

NCT07112885

Organization

Istanbul University, Department of Orthopedics and Traumatology

Document Date

September 19, 2025

Informed Consent Form

StudyTitle: ComparisonofSVF InjectionWith andWithout Microfracture in Moderate Knee Osteoarthritis
Institution: Istanbul University, Department of Orthopedics and Traumatology

Introduction

You are invited to participate in a clinical study investigating the effects of stromal vascular fraction (SVF) injection with and without microfracture in patients with moderate knee osteoarthritis. Before you decide, it is important that you understand the purpose of the study, what it involves, and any possible risks or benefits.

Purpose of the Study

The purpose of this study is to compare the clinical and radiological outcomes of two different treatment methods in patients with moderate knee osteoarthritis: (1) arthroscopic debridement and microfracture followed by intra-articular SVF injection, and (2) arthroscopic debridement followed by SVF injection alone.

Procedures

If you agree to participate, you will be randomly assigned to one of two groups. All patients will undergo arthroscopic knee debridement. Group A will receive additional microfracture and SVF injection, while Group B will receive SVF injection alone. Follow-up visits will be conducted at baseline, 3, 6, 12, and 24 months, with MRI imaging performed at baseline, 12, and 24 months.

Risks and Discomforts

Possible risks include pain, swelling, stiffness, or infection after the procedure. As with any surgical or injection procedure, there is a small risk of complications related to anesthesia or the intervention itself.

Benefits

Potential benefits may include reduced pain, improved knee function, and possible improvement in cartilage quality. However, there is no guarantee of direct personal benefit.

Confidentiality

All information collected during the study will be kept strictly confidential. Your identity will not be disclosed in any publication or report.

Voluntary Participation

Participation in this study is entirely voluntary. You may refuse to participate or withdraw at any time without giving a reason, and this will not affect your standard medical care.

Contact Information

If you have any questions or concerns about the study, please contact the principal investigator: Dr. Mehmet Yağız Yenigün Istanbul University, Department of Orthopedics and Traumatology

Consent

I have read and understood the information provided above. I voluntarily agree to participate in this study.

Participant Name and Signature: _____

Date: _____

Investigator Name and Signature: _____

Ethical Considerations

The study protocol was approved by the Institutional Review Board of Istanbul University. All patients provided written informed consent prior to participation.



Κωνσταντίνος Βασιλείου
Πρόεδρος ΔΕΠ ΟΡΘΟΠΕΔΙΑΣ

Βεβαιώνεται ότι ο ασθενής έχει ενημερωθεί και έχει δώσει την συγκατάθεση του για τη συμμετοχή του στην έρευνα.

Ο ασθενής ενημερώθηκε για τον σκοπό της έρευνας, τα οφέλη και τους κινδύνους, και δήλωσε ότι συμμετέχει εθελοντικά. Η συγκατάθεση του ασθενούς καταγράφεται σε αυτό το έγγραφο. Η έρευνα έχει εγκριθεί από την Επιτροπή Ηθικής και Κλινικής Έρευνας του Ιατρικού Πανεπιστημίου Αθηνών. Ημερομηνία: 06/04/2022. Αριθμός: 839487.

Ονοματεπώνυμο: Δρ. Ορέστης Ερμούζης
Υπογραφή: Δρ. Ορέστης Ερμούζης

Κατάσταση: Δρ. Ορέστης Ερμούζης
Αριθμός: 839487



Κλινική Αρθροπλαστική ΕΠΚ ΚΑΡΔΙΟ
ΠΕΡΙΕΡΕΥΣΗ ΤΩΝ ΕΚΤΕΡΩΝ ΔΕΞΤΕΡΩΝ
ΕΠΕΙΓΟΝΤΟΣ



Ημερομηνία: 06/04/2022

Ethics Approval-English Version

Reference: Letter of the Department of Orthopedics and Traumatology dated 06/04/2022 and numbered 839487

The study titled “**Comparison of the Clinical and Radiological Outcomes of Isolated Intra-articular SVF (Stromal Vascular Fraction–Stem Cell) Therapy with Arthroscopic Microfracture (Debridement) + SVF Therapy**”, with file number 2023/106, for which you are the principal investigator and conducted by Dr. Mehmet Yağız YENİGÜN, was reviewed at the meeting of our committee dated 20/01/2023 and numbered 02, and it was found to be ethically appropriate. The minutes of the meeting are attached.

For your information.

Document Verification Code: BSNV6R250P

PIN Code: 42152

Prof. Dr. Ali Yağız ÜRESİN

Chairman of the Committee

Note:

Asubsequent ethics committee application was submitted in order to increase the number of participants (from 40 to 50) and to update the study title. This amendment request was reviewed and approved by the committee, confirming that both the protocol modification and the revised sample size were ethically appropriate.



Sayın Doç. Dr. Ömer Naci ERGİN
Ortopedi ve Travmatoloji Anabilim Dalı

İlgi : Ortopedi ve Travmatoloji Anabilim Dalının 17/03/2025 gün ve 3241799 sayılı yazısı

Sorumlu araştırmacığımı üstlendiğiniz ve Dr. Mehmet Yağız YENİGÜN' ün yürüteceği 2023/106 dosya numaralı "İzole eklem içi SVF (Stromal Vascular Fraction-Kök hücre) tedavisinin Artroskopik Mikrokrinik (Debridman)+SVF tedavisinin klinik ve radyolojik sonuçları ile karşılaştırılması" başlıklı çalışma, kurumumuzun 20/01/2023 tarih ve 02 sayılı toplantısında görüşülerek etik yönden uygun bulunmuştur.

İlgili değişiklik isteminiz, Değişiklik Bilgi Formu, Gönüllü sayısına ilişkin değişiklik, Tez isim değişikliği " İzole eklem içi SVF tedavisinin Artroskopik debridman + SVF tedavisinin klinik sonuçları ile karşılaştırılması" Tez çalışmasının "Gonartroz Hastalarında Stromal Vasküler Fraksiyon Tedavisinde Artroskopik Mikrokrinik ile Kombinasyonun Klinik ve Radyolojik Sonuçları: Randomize Kontrollü Prospektif Çalışma" olarak değiştirilmesi hakkında, kurumumuzun 18/04/2025 tarih ve 08 sayılı toplantısında yeniden görüşülerek etik yönden uygun bulunmuş olup, tutanaklar ekte sunulmuştur.

Bilgilerinizi rica ederim.

Prof. Dr. Ali Yağız ÜRESİN
Kurul Başkanı

Ek:İstanbul Tıp Fakültesi Klinik Araştırmalar Etik Kurulu Karar Formu

Bu belge, güvenli elektronik imza ile imzalanmıştır.

Belge Doğrulama Kodu :B503BP40JC Pin Kodu :28213

İstanbul Tıp Fakültesi Dekanlığı Çapı Farklı TS/EN/ISO

Tel : 0 212 414 21 38 / 414 20 00-11561 Faks : 0 212 414 21 38 / 435 11 93

e-posta : tf-dekanligi@istanbul.edu.tr Elektronik Aj : http://istanbul.tip.istanbul.edu.tr

Kep Adresi : istanbuluniversitesi@kep.tr

Belge Takip Adresi : https://www.turkiye.gov.tr/istanbul-universitesi-ehys

Bilgi için : Çhan KILIÇ

Dağıtık : 31346



Bu belge 5070 sayılı Elektronik İmza Kanununun 5. Maddesi gereğince güvenli elektronik imza ile imzalanmıştır.

Ethics Approval-English Version

Reference: Letter of the Department of Orthopedics and Traumatology dated 17/03/2025 and numbered 3241799

The study titled ***“Comparison of the Clinical and Radiological Outcomes of Isolated Intra-articular SVF (Stromal Vascular Fraction–Stem Cell) Therapy with Arthroscopic Microfracture (Debridement) + SVF Therapy”***, with file number 2023/106, for which you are the principal investigator and conducted by Dr. Mehmet Yağız YENİGÜN, was reviewed at the meeting of our committee dated 20/01/2023 and numbered 02, and was found to be ethically appropriate.

Your request for amendment, including the Amendment Information Form, the change in the number of participants (from 40 to 50), and the thesis title modification from ***“Comparison of the Clinical Outcomes of Isolated Intra-articular SVF Therapy with Arthroscopic Debridement + SVF Therapy”*** to ***“Effect of Arthroscopic Microfracture Combined with Stromal Vascular Fraction Therapy on Clinical and Radiological Outcomes in Gonarthrosis: A Prospective Randomized Controlled Trial”***, was reconsidered at the meeting of our committee dated 18/04/2025 and numbered 08, and was also found ethically appropriate. The minutes of the meeting are attached.

For your information.

Document Verification Code: BS93BP48J8C

PIN Code: 26213

Prof. Dr. Ali Yağız ÜRESİN

Chairman of the Committee

