

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

January 20, 2023 (The date on the cover page (January 20, 2023) was intentionally indicated to reflect the official ethics committee approval date of the study protocol, as required for regulatory documentation)

Informed Consent Form

Study Title: Effect of Arthroscopic Microfracture Combined with Stromal Vascular Fraction Therapy on Clinical and Radiological Outcomes in Gonarthrosis: A Prospective Randomized Controlled Trial
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. All participants will undergo arthroscopic 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.

Tarih ve Sayı: 30.01.2023-1603453
T.C.
İSTANBUL ÜNİVERSİTESİ
İstanbul Tip Fakültesi Dekanlığı
Klinik Araştırmalar Etik Kurulu

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

lige : Ortopedi ve Travmatoloji Anabilim Dalının 06/04/2022 gün ve 839487 sayılı yazısı
Sorumlu araştırmacılığı üstlendiğiniz ve Dr. Mehmet Yağız YENİĞÜN¹ün yürüteceği 2023/106 dosya numaralı, "İzolda eklemi² SVF/Stromal Vacular Fibrosis (Kök hücre) tedavisiin Artrioskopik Mikrokirurgi (Debridman) SVF³ tedavisinin klinik ve radyolojik sonuçları ile karşılaştırılması" başlıklı çalışma, 2001/01/2023 tarih ve 02 sayılı toplantıda görüşüllererek etik yönden uygun bululmus olup, turutankalar ekte sunulmuştur.

Bilgilerinizi rica ederim.

Prof. Dr. Ali Yağız ÜRESİN
Kurul Başkanı

Bu belge, geleneksel elektronik imza ile imzalanmıştır.
Belge Doğrulama Kodu: BSNV8R250P Pın Kodu: 4K151
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İstanbul Teknik Üniversitesi Dekanlığı Cephe No:TS/STANBUL
Tarih: 02.11.2014 Sayı: 00-31561 Faks: 0212 414 21 38 / 635 11 93
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Dahili: 51346

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

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:

A subsequent 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.

Tarih ve Sayı: 21.04.2025-3285507



T.C.
İSTANBUL ÜNİVERSİTESİ
İstanbul Tıp Fakültesi Dekanlığı
Klinik Araştırmalar Etik Kurulu



2025 AYLIK YILI

Sayı :E-29624016-050 99-3285507
Konu :Doç. Dr. Ömer Naci ERGIN h.k.

Sayın Doç. Dr. Ömer Naci ERGIN
Ortopedi ve Travmatoloji Anabilim Dalı:

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

Sorumlu araştırmacılığını üstlendiniz ve Dr. Mehmet Yağız YENİGÜN'ün yürüreceği 2023/106 dosya numaralı “İzole eklemiçi SVF (Stromal Vascular Fraction-Kök hücre) tedavisiinin Arthroskopik Mikrokirir (Debridman)+SVF tedavisinin klinik ve radyolojik sonuçları ile karşılaştırılması” başlıklı çalışma, kurulumuzun 20/01/2023 tarih ve 02 sayılı toplantıda etik yönden uygun bulunmuştur.

İlgili değişiklik isteminiz, Değişiklik Bilgi Formu, Gömülü sayısına ilişkin değişiklik, Tez isim değişikliği “İzole eklem içi SVF tedavisiinin Arthroskopik debridman + SVF tedavisinin klinik sonuçları ile karşılaştırılması” Tez çalışmaların “Gonartreoz Hastalarında Stromal Vasküler Fraksiyon Tedavisinde Arthroskopik Mikrokirir ile Kombinasyonun Klinik ve Radyolojik Sonuçları: Randomize Kontrollü Prospektif Çalışma” olarak değiştirilmesi hakkında, kurulumuzun 18/04/2025 tarih ve 08 sayılı toplantıda yeniden görüşüllererek 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 Değiştirme Kodu: BSNV6R250P Pin Kodu: 26213
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Kep Adresi : istanbuluniversitesi@hso1.kep.tr



Bu belge 5070 sayılı Elektronik İmza Kanunu'nun 5. Madde ile gerekçinde 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

