Informed Consent to Join Study Uploaded 27th July 2026

Study Title: Total Osteo-Cartilage Replacement (TOCR) in the management of Osteoarthritis of .the knee
Protocol Number: 113110 Version 105
Principal Investigator: AlSalam Specialist Hospital, Bahrain
Your doctor, Dr Jamal Saleh, AlSalam Specialist Hospital, Bahrain [Telephone number .+97336599999], is conducting a prospective study to treat Osteoarthritis of the Knee

PURPOSE OF THE STUDY

The probability of developing Osteoarthritis of the Knee (OAK) in the Bahraini population is 40 % by the age they reach 50 years, and there is no permanent treatment as of now. Total knee replacement is the final treatment and has many complications and restrictions on physical .activities

:ESSENTIAL ELEMENTS
Study Title: Total Osteo-Cartilage Replacement in the management of Osteoarthritis of the .1 .knee

NHRA clinical trial approval code (REC code for Phase I Clinical Trial)

Names and affiliations of the principal investigator
Dr Jamal Saleh, AlSalam Specialist Hospital, Bahrain [Telephone number +97336599999] is .conducting a prospective study to treat Osteoarthritis of the Knee

.Sponsor of the study: Prof Sadat A AlAli, Dr Hussain Al Omar and Dr Omar Dahluli

:Subject selection criteria
Patients <70 years
.No Varus or Valgus deformities
.Presence of intact Anterior and Posterior cruciate ligaments
.Agree to follow up on a regular basis

:Purpose of the research

This is the Phase I clinical study in which bone allografts will be used instead of metallic and .polyethylene implants
The probability to develop Osteoarthritis of Knee (OAK) in Bahraini population is 40 % by the age they reach 50 years and there is no permanent treatment as of now and total knee replacement is the final treatment and has many complications are reported in Total knee .replacement and restriction of physical activities
.The study was part of similar research and was carried out as early as 1975
.The surgery and the allograft will be provided free of charge by the sponsors
The purpose of this study is to use bone allografts instead of metallic and polyethylene implants .and test the efficacy of this type of treatment

Patients will be required to follow up for a period of 36 months every 3, 6,9, and 12 months, .and then 6 months twice a year during the second year and once in the third year
Patients will be screened initially for Osteoarthritis of the knee, assessment of no deformities, and presence of both cruciate ligaments clinically, and if needed, using MRI. Once the size of the .condyles is ascertained, the allografts will be ordered
Once the allografts are received, patients will be operated on using the standard technique, and instead of metallic implants, allografts will be fixed using 2 Acutrak 2, 7.5mm X 120mm long .headless screws
Patients will remain in the hospital for 5 days and will be discharged. Patients will come for Outpatient clinics after 2 weeks for removal of sutures and then every 3rd month or as needed .in case of any adverse event

Risks and discomforts

There is no increased risk of the surgery apart from initial pain and discomfort, which happens after any surgical operation. Appropriately, pain management will be undertaken for every patient as the sponsors are undertaking the financial cover for any unforeseeable complications. Patients will be informed in detail about the clinical risk of the research and options by regular TKR. In the present surgery the side effects can be due to failure of the graft to unite. One study reported that in fractures the success rate of union was 83% and in another study of 2025 the Radiological signs of union were achieved in most patients within three to six months. Pain score improved significantly over time, with VAS scores decreasing from 6-8 at one month to 1-3 at six months. Functional recover followed a similar pattern, with WOMAC scores improving from 65-80 at one month to 85-98 at six months, indicating substantial progress in joint mobility, weight-bearing ability, and pain reduction. In case the union does not take place in 6-8 months period additional bone graft will be added or the surgery will be done with the standard Total knee replacement

Lakhwani OP, Jindal M, Agarwal S, Garg K. Efficacy of Allogenic Bone Graft Per Se and when Augmented with Various Adjuvants in Fracture Healing. Ortho & Rheum Open Access J 2018; .11(4): 555820. DOI: 10.19080/OROAJ.2018.11.555820

Kumar A, Venkataraman S, S N J, et al. (April 17, 2025) Functional and Radiological Outcomes of Allograft Application in Distal Femur Fractures: A Retrospective Study. Cureus 17(4): e82473. doi:10.7759/cureus.82473

Benefits: After the recovery period, participants are expected to regain a full range of movements and return to a normal lifestyle, similar to their younger years. Lastly, the expectation of the implants to survive is way longer than the traditional implants of Total Knee .replacement (TKR)

:Alternatives

There is an alternative to the TOCR, and this is Total Knee Replacement, which has its own complications. The benefit of TOCR in comparison to the regular TKR is that with TOCR, the normal lifestyle can be maintained, like praying, recreational sporting activities, and longevity of the implants. Both procedures, TKR and TOCR, can have complications. The infection rate in TKR can reach up to 13% (Ribeiro M, Monteiro FJ, Ferraz MP. Infection of orthopedic implants with emphasis on bacterial adhesion process and techniques used in studying bacterial-material interactions. Biomatter. 2012 Oct-Dec;2(4):176-94) compared to 0.04% in TCR (Update: Allograft-Associated Bacterial Infections --- United States, 2002 MMWR (March 15, 2002 / .51(10);207-210)

The TKR of a joint is at present standard of care and the allograft is being used for the first time .for both Femur and Tibia

Different allografts have been in use since 1880, and it is estimated that more than 500,000 bone grafting procedures are completed each year in the United States, with much lower complications than implant surgeries. (Bostrom MP, Seigerman DA. The clinical use of allografts, demineralized bone matrices, synthetic bone graft substitutes, and osteoinductive growth .factors: a survey study. HSS J. 2005 Sep;1(1):9-18

Allografts are taken from healthy donors, and extensive tests through rigorous screening using donor medical and social histories, along with microbial testing of recovered tissue and viral .testing of donor serum, are conducted to rule out any overt disease process

These include steps to prevent processing tissues with unacceptable bioburden through rigorous screening using donor medical and social histories, along with microbial testing of recovered tissue and viral testing of donor serum. Potential bioburden is also controlled through aseptic recovery and processing methods and then reduced through disinfection steps that can include antibiotics, detergents, mechanical processes, chemical solutions, and terminal .sterilization

Processing steps may also include decellularization methods to lower the immunogenic potential of some tissues. To enhance the fusion potential of bone void fillers, demineralization steps may be used, and the resultant demineralized bone matrices may be combined with a carrier to improve handling. To preserve relevant biological, biochemical, and physical properties of allografts for clinical use and ease of handling, a number of methods may be used, which include: (1) refrigeration in media, (2) freeze-drying, (3) cryopreservation, (4) freezing, .and (5) media storage at room temperature

:9B: TOCR Procedure

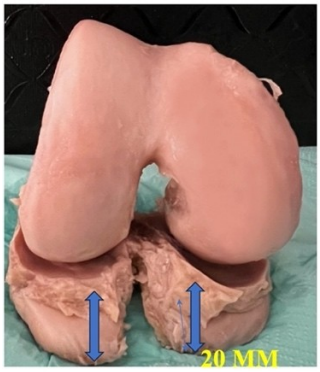
In TKR, the metallic and polyethylene implants are used, while in TOCR, natural allografts are .used from donors

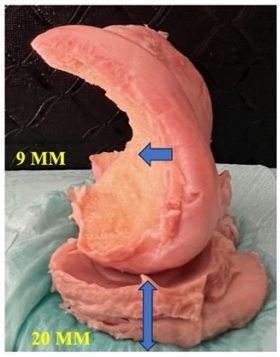
:Implants of TKR

Implants of TKR



:TOCR Natural Allograft





1.Femoral cartilage with 9 mm of cancellous bone

2. Tibial Plateau 20 mm thick with Both intact Meniscus.

:TOCR Natural Allograft

.9C. Comparative Differences between TOCR and TKR

	Variable	TOCR using Allograft	TKR (Metallic Implants)
.1	Used since	1880	1968
.2	Duration of Surgery	hours 2	hours 2
.3	Blood Loss	100-150ml	100-150ml
.4	Physiotherapy	Required	Required
.5	Range of Movement	Normal	Limited
.6	Failure of Implants	Possible	Possible
.7	Physical Activity	Near Normal	Restricted

.8	Infection	0.04%	Maximum up to 13%
.9	Revision	Easy	Difficult
.10	**Longevity**	**Expected 20 years Plus**	years 10-15

:Confidentiality

All Patients' identities will be kept highly confidential, and as any clinical trial mandates require, will be kept for 25 years before being destroyed. The blinded data might be used for .publications and presentations

:Cost and compensation
Once enrolled, the cost of Implants (BD6000.00) + operating cost will be borne by the sponsors, including the follow-up visits. No other compensation will be offered additionally if any treatments are required due to the surgery, which will be covered by the insurance, which will .be paid by the sponsors. Any travel involved will be compensated
The insurance policy will cover all costs of treatment required due to any side effects or .complications of the TCR procedure
In case of failure of the allograft the sponsors/Insurance will undertake to replace the joint with .the standard knee replacement

:Research questions

.If Patients require further explanation of the clinical trial, they can contact the following
Dr Jamal Saleh, AlSalam Specialist Hospital, Bahrain Telephone Principal Investigator: number +97336599999
Prof Sadat A. AlAli (Tel # +97339309939) Sponsors:
Dr Hussain Al Omar (Tel# +97336464590)

Contact information of the IRB/IEC (for questions about the subject's rights as a human subject .or concerns about the research)
Contact information of the NHRA representative (for any complaints or concerns about the .research)

:Voluntary participation

To join this clinical trial is absolutely Voluntary, and there is no penalty for not joining. All patients who join the trial and undergo surgery should follow up for at least 12 months. After this period, the individual may discontinue participation at any time without penalty or loss of .benefits to which they are otherwise entitled

Clinically relevant research results
Once the follow-up of 36 months is completed, all the information related to the Clinical Trial will be available on the website of the hospital, and under freedom of information, will be .personally provided to all the patients

Publicly available information
A description of the clinical trial will be available on http://www.ClinicalTrials.gov, as required " by NHRA-CT Regulations. This website will not include information that can identify any patients at most, the website will include a summary of the results. You can search the website at any .time
:Consent discussion
The informed consent will be that the patients have read the details and risks explained To the complete satisfaction of me and any caregivers, like husbands/guardians. All my queries were answered to my satisfaction. I understand that my participation is voluntary and that I may withdraw my participation at any time without penalty. I am over 21 years of age and I ".voluntarily agree to participate in this research study

:Additional Items of the Informed Consent

:Possibility of unforeseeable risks

Patients also give consent that the intervention may involve unforeseeable risks, and if it occurs, .will be taken care of by the sponsors

.Potential termination without regard to consent
If, due to unavoidable circumstances, the trial has to be discontinued, all operated patients will .be followed up, and the new patients will not be enrolled
Additional costs
.Any additional costs in the treatment due to the surgery will be undertaken by the sponsors
Withdrawal
A patient can withdraw from the trial before the surgery is performed. Once the surgery is .performed, patients need to be followed up for reporting and to take care of any complications
New findings
Any new data on the study that comes out will be released to the patients during the course of .the follow-up

.Sample size: The number of patients in the trial is expected to be 10 (ten)

.**Future research:** The samples removed from the bone will not be used for future research
".NO, you may NOT use my samples for future research
.Commercial use of biospecimens: None
.Genome sequencing: Not Applicable

?Whom do I CONTACT IF I NEED MORE INFORMATION OR HELP
Should you need additional information, or if you experience any side effects, or in case of :injury, please contact
Dr Jamal Saleh (PI) AlSalam Specialist Hospital, Riffa, Bahrain
Phone No. +97336599999

Consent to Release Information: Attachment 1
Signature Page
o become part of this study, and to authorize use and disclosure of your personal health
.information, you or your legal representative must sign and date this page
:By signing this page, you are confirming the following
You have read all of the information in this Consent to Release Information, and you have had
.time to think about it
.All of your questions have been answered to your satisfaction
You are volunteering to be part of this observational study, and you understand that you may
.freely choose to stop being part of this study at any time
You allow the study doctor and the sponsor to use and disclose your personal health
.information as described in this document
You have received a copy of this signed Consent to Release Information form to keep for
.yourself
Patient Name [ ] Patient Initials and Number
[ ] Signature of Patient: [ ] [Patient must personally date

*Signature of Legally Acceptable Representative (if applicable)
Date [ ] [Legally Acceptable Representative must personally date] Legally Acceptable
[ ] Representative Name
If signed by a Legally Acceptable Representative, a description of the relationship to the patient
.or other basis of legal authority
:Date Witness: (Unrelated). Name

Signature