National Guard Health Affairs
King Abdullah International Medical Research Center
الشؤون الصحية بالحرس الوطني
مركز الملك عبدالله العالمي للابحاث الطبية

Interventional studies

Informed Consent Form

1. Study Information:

Study Title: prospective randomized trial evaluating the role of genicular artery embolization versus genicular nerve ablation in treatment of persistent pain in patients with severe knee osteoarthritis.	
Study No.: ICT23J/003/11	
Principal Investigator: Dr. Omar Batouk	**Sponsor:**
Principal Investigator Address: King Abdulaziz Medical city, National guard hospital, Jeddah – Orthopedic department	

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APPROVED
IRB
Institutional Review Board

2. Introduction : You are being invited to take part voluntarily in a local research study being conducted in King Abdulaziz Medical city National guard Hospital because you have Knee Osteoarthritis which is resistant for conservative treatment

3. Study Purpose:

The purpose of this project is to evaluate the role of genicular artery embolization versus genicular nerve ablation in treatment of persistent pain (as primary objective) and assessing knee function (as secondary objective) in patients with severe knee osteoarthritis.

4. Duration of Participation: The duration of participation is approximately one year, where pain and function will be assessed after you have your procedure either radiofrequency ablation or embolization then you will be followed up for around 9 months in 3 visits, you will visit the clinic 6 weeks, 3 months, and 6 months after the procedure, and you will be asked to complete a questionnaire

5. Number of Subjects participating/ study Area and settings:

The total number expected to participate on this study is 321 participants, this study will be conducted in King Abdulaziz Medical City, National guard hospital, Jeddah, Saudi Arabia

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Cooperation will be between the orthopedic surgery department and interventional radiology suite in achieving the objectives of this research.

Inclusion Criteria:
Adults more than 18 years both gender with knee osteoarthritis Kellgren-Lawrence score of 3 minimum Resistant to conservative therapy at least 3 months . (Conservative therapy includes: NSAIDS, physiotherapy, weight reduction program, Intraarticular injections)
patients with multiple comorbidity who need to undergo operative procedure like total knee arthroplasty for their pain but they cannot because of their medical status

Exclusion criteria:
Adults with knee osteoarthritis who underwent procedure such as knee arthroplasty in the same affected knee.
Known case of malignancy or local infection or rheumatoid arthritis or prior Intraarticular injection in the ipsilateral knee in the last 6 months, body weight greater than 150 kg, renal Impairment or irreversible coagulopathy and peripheral vascular disease.
The included patient population will be selected from King Abdulaziz Medical City, National guard hospital, Jeddah, Saudi Arabia.

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6. Study Procedures:

Before you agree to join in this study, Please take time to read the information provided below. (Please read the information carefully and discuss it with any one you want for the right advice. This may include a friend, a relative or family doctor)
Opaque envelope randomizing technique will be used for randomization in which all of the subjects will be given a theoretical number and put in an envelope and then will be randomly chosen to be a part of one of the three following limbs of our study.

First limb: The control limb which will be on regular conservative treatment. (NSAIDS, physiotherapy, weight reduction program, Intrarticular injections).

Second limb: Patients who will undergo radiofrequency ablation. (explained below).

Third limb: Patients who will undergo genicular artery embolization. (explained below).

Genicular nerve radiofrequency ablation (RFA) is a 2-step procedure. diagnostic block under fluoroscopy 1 mL of lidocaine is injected around the genicular nerve branches.

Genicular artery embolization (GAE) is embolizing of 1, 2, or 3 genicular arteries supplying the location of the subject's pain

You will be randomized to either conservative management or radiofrequency ablation or embolization and There is 33% chance that you will receive any one of the three mentioned management methods

If you agree to be in this study, you will be requested to sign this Informed Consent Form.
and you are required to fill in a questionnaire to assess the pain and function then after doing the procedure you will be asked to attend orthopedic clinic to fill in the same questionnaire in the following manner to reassess pain and function.

Visit 1: 6 weeks after the procedure
Visit 2: 3 months after the procedure
Visit 3: 6 Months after the procedure

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7. When will my participation end?

Study participation completed after following up the patient for 6 weeks, 3 months, and 6 months after the procedure is done

8. Risks and inconveniences

There will be no additional risks or inconveniences from the choice of the study guidance techniques, however there are risks and complications that may occur with the procedures which will be mentioned, discussed and signed on procedure consent. No extra clinic visits other than the surgery follow ups will be asked. You will be informed with any new information occurred that may affect your desire to start or continue the study.
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The vast majority of patients who undergo RFA report no severe complications. However, some studies have demonstrated a small risk for injury to surrounding nerves or vessels, hematoma formation, infection, hypoesthesia, skin necrosis, or infection.
The vast majority of patients who undergo GAE report no severe complications. However, some studies have shown a small risk for hematoma formation, skin ulceration or discoloration, skin necrosis or focal bone or fat infarcts.

9. Important information regarding females participation in the study:

There will be no effect of female or female partner participation on the study and pregnant women will not have this procedure as it may contain radiation exposure

10. Costs and compensation for participation in this study

You will not receive any compensation for your participation in this trial. You will not be asked to pay for any procedure, drug, and laboratory test related to the study However, in the event of an illness or injury related to the study procedures as per the decision of the principal investigator of the study, all treating procedures, follow-ups, hospitalization will be compensated

11. Benefits:

I know that there will be no direct benefit for me or my relatives from participation in this study but it may help in improvement of knowledge or medical science progress.

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12. Alternative Treatment(s)

If you do not agree to participate in the study, you will continue to be on conservative treatment for knee osteoarthritis, and you will not go for any of the other procedures

13. Information about participation

Your participation in this study is totally voluntary, you have the right to withdraw at any time you want without mentioning the reasons. If you do not want to take part, you will receive standard care provided by your doctor, and your decision about the study will not affect your current or future medical care.

The study doctor and the study sponsor have the right to withdraw you from the study if he decided that it's better for your medical condition. or you did not comply with study requirements.

If you consider participation of this study you will have to complete assessment questionnaires at follow up visits as previously mentioned until the last visit 6 months after the procedure

If you have any other diseases or adverse events the principal investigator will decide whether to continue with participation in the study or not.

14. Confidentiality and Authorization to collect, use and disclose Personal Medical Information

All information related to you including personal and medical data provided and collected by the study doctor or coordinator and recorded in the study records will be handled as confidential and no one except authorized research team at King Abdullah International Medical Research Center (KAIMRC), Sponsors, Institutional Review Board (IRB), Research Scientific Committee (RC), Ministry of Health auditors including but not limited to US Food and Drug Administration (FDA), the European Medicines Agency (EMA), the Saudi Food and Drug Administration (SFDA) and related personnel that can have access to record, review and analyze them.

All the information collected in subjects records belong to King Abdullah International Medical Research Center or industry sponsor , in case any results of the study are published , your personal information will never be mentioned, it may be coded in symbols known for research team

15. Communication

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In case of any research related inquiries or medical care during study, or any injuries, emergency cases feel free to contact the study principal investigator Dr. Omar Batouk through the number: 0541111849

In case you have enquiries related to your rights as a research subject you can contact the Institutional Review Board on Tel. 8011111 Ext. 14572.

I've been given the opportunity to discuss my questions about participating in this study and the research team has answered all my questions, if I have any further questions I will call Dr. Omar Batouk

I understand that my participation in this research is voluntary and I know that I have the right to withdraw when I decide without affecting the medical care that I receive usually and also understand that the principal investigator has the right to end my participation as it deems appropriate to me.

And I also understand that non-compliance with research procedures and/or the visits dates might end my participation in this study.

I understand that every clinical trial must be registered in a publicly accessible database before recruitment of the first subject.

By signing this informed consent form I acknowledged that I did not give up any of my legal rights, also I confirm that I have received a sufficient information about the study and that I have read and understood the information in this informed consent form and I have had the opportunity to discuss the study and ask questions and have been satisfied with the received explanations.

I understand that after signing this informed consent form I will receive a signed and dated copy.

By signing and dating this informed consent form, I agree to participate in this research study.

Subject Name	**Signature**	**Date**

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Name of the legal guardian Type if the patient is minor(less than 18 years)	**Signature**	**Date**
Name of the witness Type if the subject agrees verbally and he/she is illiterate	**Signature**	**Date**
Name of the Principal Investigator	**Signature**	**Date**
Person who discussed the consent	**Signature**	**Date**

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