

Can infected knee joints be treated without surgical washout?

Submission date 13/01/2024	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 24/02/2024	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 27/01/2025	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

A painful, hot swollen joint is a common medical emergency presentation of a patient that can be attributed to a wide differential diagnosis. The most serious of these is septic arthritis (SA). Delayed or inadequate treatment of SA may lead to irreversible joint damage resulting in disability and economic consequences. The byproducts of microorganisms released during infection and inflammation can rapidly induce articular cartilage destruction. As the adult articular cartilage has poor regenerative capacity, this process may lead to irreversible cartilaginous damage resulting in a dysfunctional joint even if the primary infection is cured with antibiotics. Thus, emergency treatment of SA should be promoted to remove purulent material from the joint space. This can be achieved either surgically (arthroscopy or arthrotomy washout) or medically (arthrocentesis). Although early drainage is essential to minimize the risks of permanent loss of articular function, it is unclear whether the optimal approach involves arthroscopic lavage or arthrocentesis; surgeons appear to prefer surgical lavage because their training routinely considers septic arthritis to be a closed-space infection comparable to an abscess, whereas rheumatologists appear to prefer daily arthrocentesis because of its ease and non-invasive nature. There is a lack of prospective data comparing the two approaches, where the literature is largely retrospective. The proposed study will answer the question surrounding the beneficial effects of serial knee aspirations/arthrocentesis in the management of the native joint's SA, by reporting the functional and clinical outcomes of patients diagnosed with SA who will be treated with arthrocentesis. The participant will still receive antibiotic treatment according to the hospital's protocol. The hypothesis is that arthrocentesis is effective and not inferior to surgical joint wash-out in treatments of knee septic arthritis.

Who can participate?

Patients aged 18 to 100 years old with septic knee arthritis

What does the study involve?

This study aims to demonstrate the beneficial effect of serial knee aspirations without surgical washout. While the surgical washout is a standard of usual care treatment along with antibiotics, the study team are trying to prove that there might be no need for surgical washout and it is enough to do knee aspiration as a simple bedside procedure.

What are the possible benefits and risks of participating?

The benefit of participating is to avoid the standard surgical treatment in infected knee joints. While that might be a huge benefit if proven, there might be a risk of residual infection if the knee washout is not done. Although such risk is more of a theoretical risk rather scientifically proven risk.

Where is the study run from?

Sultan Qaboos University Hospital (Oman)

When is the study starting and how long is it expected to run for?

October 2023 to October 2027

Who is funding the study?

Sultan Qaboos University Hospital (Oman)

Who is the main contact?

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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

KNEE AI (Knee NEEdle Aspiration for Infection) Trial: Serial knee aspirations for the treatment of native septic arthritis in adults. Single Arm Phase II trial

Acronym

KNEE AI Trial

Study objectives

The proposed study will try to answer the question surrounding the beneficial effects of serial knee aspirations/arthrocentesis in the management of the native joint's SA, by reporting the functional and clinical outcomes of patients diagnosed with SA who will be treated with arthrocentesis. The participant still will receive antibiotic treatment according to the hospital's protocol.

The hypothesis is that arthrocentesis is effective and not inferior to surgical joint wash-out in treatments of knee septic arthritis.

Ethics approval required

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Ethics approval(s)

approved 28/11/2024, Sultan Qaboos University Research Ethical Committee (Muscat, Muscat, 113, Oman; +968 2414 3427; mrec@squ.edu.om), ref: 302\2023

Study design

Single arm phase II trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Septic knee arthritis

Interventions

The intervention involves serial aspirations and IV antibiotics. The involved joint will be prepped and draped in a sterile fashion before arthrocentesis. Aspiration of the joint will be done using an 18- or 20-gauge needle on a 20mL syringe. The skin will be entered perpendicularly and the needle will be directed posteriorly behind the patella, toward the intercondylar notch or supra-patellar region. As much infected joint fluid will be removed as possible.

The intervention will be performed by an orthopaedics specialist or resident who is conformable to do the knee aspiration.

The delivery mode will be face-to-face for all participants individually.

The location will be the hospital where the patient is admitted, no infrastructure is needed.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Failure of treatment and proceeding with standard surgical washout measured using laboratory methods for the inflammatory markers, C-reactive protein (CRP) and white blood cell (WBC) count at baseline, then every 48hrs for 10 days

Key secondary outcome(s)

Knee pain and functional scores measured using a knee Visual Analog Score (VAS) and knee the functional Western Ontario and McMaster University Osteoarthritis Index (WOMAC) at 2 weeks, 3 months and 6 months

Completion date

01/10/2027

Eligibility

Key inclusion criteria

1. Informed consent to participate in the trial
2. Patient demographic data (Age, sex, knee side). Age 18yrs and above
3. Patients' comorbid
4. Pre-aspiration data (Knee pain, swelling, redness, ROM actively and passively, WOMAC, VAS score, Inflammatory marker, Counts, Gram Stain and Culture results, Antibiotic if initiated before or after antibiotics)
5. Repeat labs every 48 hours by CBC and CRP
6. Repeat aspiration every clinical recollection noted and/or patient worsening in clinical /laboratory markers
7. Max aspirations are 3 times, then label as failed and proceed to standard washout
8. F/u 2 weeks, 3 months, and 6 months. Each with VAS and WOMAC functional scores

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

100 years

Sex

All

Key exclusion criteria

1. Infected prosthetic joints
2. Adjacent osteomyelitis preceding joint infection
3. Septic arthritis occurs as an incidental event late in the course of an otherwise fatal illness
4. Patients that are 17 years old or less
5. Reactive or Inflammatory arthritis
6. Polyarticular joint involvement
7. Symptoms more than 1 week

Date of first enrolment

15/12/2024

Date of final enrolment

01/04/2027

Locations**Countries of recruitment**

Oman

Study participating centre**SQU Hospital**

Muscat

Muscat

Oman

113

Sponsor information**Organisation**

Sultan Qaboos University Hospital

ROR

<https://ror.org/049xx5c95>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Sultan Qaboos University

Alternative Name(s)

SQU

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Oman

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available Excel sheet, locked by a password and belong to the hospital system. Only the data collector and PI/Co-PI can access the data draw. All the measured outcomes along with patient demographic data are stored, and each participant will be labelled by number. The data will not be accessible to the public or any other healthcare provider. As part of participation, the patient has to give consent and will be recorded in the hospital system. These data will be stored for 10 years and then discarded.

IPD sharing plan summary

Stored in non-publicly available repository