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Can infected knee joints be treated without surgical washout?

Submission date
13/01/2024

Recruitment status
Recruiting

Registration date
24/02/2024

Overall study status
Ongoing

Last Edited
27/01/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English Summary
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?
Dr Humaid Al Farii, Humaid44@squ.edu.om

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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 hypothesis
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
Ethics approval required

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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)

Treatment

Participant information sheet
No participant information sheet available

Condition
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 measure
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

Secondary outcome measures
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

Overall study start date
01/10/2023

Overall study end date
01/10/2027

Eligibility

Participant 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

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
40

Participant 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

Recruitment start date
15/12/2024

Recruitment end date
01/04/2027

Locations

Countries of recruitment
Oman

Study participating centre
SQU Hospital
Muscat
Muscat
Oman
113

Sponsor information

Organisation
Sultan Qaboos University Hospital

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Sponsor type
Hospital/treatment centre

Website
https://www.squ.edu.om/

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

Publication and dissemination plan
Planned publication in a peer-reviewed high-impact orthopedics journal

Intention to publish date
01/10/2027

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