

Assessing the efficacy of polyacrylamide hydrogel which is injected into the joints of patients suffering from arthritis in their synovial joints (knee, shoulder etc) instead of steroid injections or joint replacement surgery

Submission date 03/05/2026	Recruitment status Not yet recruiting	☒ Prospectively registered ☐ Protocol
Registration date 15/06/2026	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 07/09/2026	Condition category Musculoskeletal Diseases	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Osteoarthritis is a common condition that causes pain, stiffness, and reduced movement in joints such as the knee, shoulder, hip, or ankle. Many people are treated with pain relief medicines or steroid injections, and some may eventually need joint replacement surgery. This study is looking at whether a gel injection called polyacrylamide hydrogel can reduce pain and improve joint movement for people with osteoarthritis. The aim is to see if this injection could be a longer lasting and less invasive option than repeated steroid injections or surgery.

Who can participate?

Adults aged 18 years or over who have ongoing pain from osteoarthritis or other similar joint problems may be able to take part. Participants need to have symptoms that have not improved enough with standard treatments and where their clinician believes a joint injection is appropriate. People with joint infections, certain inflammatory joint diseases, recent surgery or injections to the same joint, or who are pregnant or breastfeeding will not be able to take part.

What does the study involve?

Participants will receive a single injection of polyacrylamide hydrogel into the affected joint as part of their usual NHS care. The injection will be guided by ultrasound, given under local anaesthetic, and carried out by trained clinicians using sterile techniques. After the injection, participants will be followed for up to two years. During this time, they will be asked to complete questionnaires about their pain, joint function, and quality of life. Most follow-up will be done remotely, so extra hospital visits are usually not needed. Information about any side effects, further treatments, or later surgery will also be collected.

What are the possible benefits and risks of participating?

Some participants may experience reduced pain, better movement, and an improved quality of

life, although these benefits cannot be guaranteed. The risks are similar to those of standard joint injections and may include short term pain, swelling, or bruising at the injection site. Infection is rare. It is also possible that the injection may not improve symptoms.

Where is the study run from?

The study is run from University Hospital Southampton NHS Foundation Trust, with plans to include other hospitals across the United Kingdom.

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

The study is expected to start after ethics approval, with the first participants planned from December 2027. It is expected to run until January 2029.

Who is funding the study?

University Hospital Southampton NHS Foundation Trust (UK).

Who is the main contact?

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Contact information

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356371

Study information

Scientific Title

Intra-articular Polyacrylamide hydrogel for Synovial Joint Arthritis. A comprehensive review of the efficacy of Polyacrylamide hydrogel in patients for whom a steroid injection or arthroplasty is warranted

Study objectives

This study aims to assess the efficacy of intra-articular polyacrylamide hydrogel as a non-operative management for patients suffering from synovial joint osteoarthritis. This is an observational pilot study which aims to assess the efficacy of polyacrylamide hydrogel as an intra-articular injection in patients who are candidates for a corticosteroid injection or arthroplasty. This study aims to assess the efficacy of the intra-articular polyacrylamide hydrogel using patient reported outcome measures (PROMS) up to two years following administration of the injection and complications from this intervention to determine the efficacy of the intervention as an alternative to arthroplasty and steroid injections.

Ethics approval required

Ethics approval required

Ethics approval(s)

Not yet submitted

Primary study design

Observational

Secondary study design

Longitudinal study

Study type(s)

Health condition(s) or problem(s) studied

Osteoarthritis (OA)

Interventions

This study is a prospective observational clinical study designed to evaluate the safety, feasibility, and clinical effectiveness of ultrasound-guided intra-articular injection of polyacrylamide hydrogel for the treatment of symptomatic synovial joint arthritis. Adult patients attending participating surgeons' outpatient clinics will be screened for eligibility during routine clinical care. Potentially eligible patients will be identified through clinical assessment and review of referral information. Potentially eligible patients will be provided with a Participant Information Sheet (PIS) by a

member of the research team following identification in the outpatient clinic. The PIS will explain the purpose of the study, study procedures, potential risks and benefits, data handling arrangements, and the voluntary nature of participation.

Participants will be given adequate time to read the information and consider whether they wish to participate. They will have the opportunity to ask questions and discuss the study with members of the research team before making a decision.

Participation in the study is entirely voluntary. Patients will be informed that choosing not to participate, or withdrawing from the study at any time, will not affect their ongoing clinical care or their relationship with the clinical team.

Written informed consent will only be obtained once the participant has had sufficient time to consider the information provided.

Once consent has been obtained, participants will be enrolled in the study and the clinical team will proceed with the standard clinical pathway, including submitting a request for ultrasound-guided intra-articular injection as appropriate.

Participants will undergo a single ultrasound-guided intra-articular injection performed by appropriately trained clinicians under local anaesthesia using established aseptic techniques. Prophylactic antibiotics will be administered where appropriate.

Participants will be followed for up to two years following the intervention. Outcome data will be collected primarily through remote patient-reported outcome measures, including validated joint-specific functional scores, pain scores, and quality-of-life assessments. Information on complications, additional treatments, and any subsequent surgical interventions will also be collected.

Data will be analysed using descriptive and appropriate inferential statistical methods to assess changes in outcomes over time and evaluate the safety profile of the intervention. Results will be reported in aggregate form.

Intervention Type

Device

Phase

Phase III/IV

Drug/device/biological/vaccine name(s)

Arthrosamid®

Primary outcome(s)

1. Knee outcome measured using Oxford Knee Score at baseline, 6 months, 12 months and 24 months
2. Foot & Ankle outcome measured using Manchester-Oxford Score MOX-FQ at baseline, 6 months, 12 months and 24 months
3. Shoulder outcome measured using Oxford Shoulder Score at baseline, 6 months, 12 months and 24 months
4. Wrist outcome measured using DASH score at baseline, 6 months, 12 months and 24 months
5. Pain measured using visual analogue scale at baseline, 6 months, 12 months and 24 months
6. Quality of life measured using EQ5D at baseline, 6 months, 12 months and 24 months

Key secondary outcome(s)

1. Prevalence of complications & adverse events measured using patient notes at annual check up to two years follow-up following recruitment to the study
2. Requirement for additional treatments, including repeat injections or surgical intervention during the follow up period measured using patient notes at annual check up to two years follow-up following recruitment to the study

Completion date

01/09/2029

Eligibility**Key inclusion criteria**

1. Adults aged 18 years or over
2. Diagnosis of symptomatic synovial joint pathology considered suitable for intra-articular injection by the treating clinician.
3. Clinical and/or radiological evidence of joint disease affecting the target joint
4. Persistent symptoms despite standard conservative management, including pharmacological and/or non-pharmacological treatment where appropriate
5. Ability to understand the study requirements and provide written informed consent
6. Willingness and ability to comply with study procedures and follow-up assessments

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 Years

Upper age limit

100 Years

Sex

All

Total final enrolment

0

Key exclusion criteria

1. Age under 18 years
2. Active local infection at the injection site or systemic infection
3. Previous intra-articular injection to the target joint within the preceding 6 months
4. Previous surgery to the target joint within the preceding 6 months or planned surgery during the study period
5. Known hypersensitivity or contraindication to the study intervention, local anaesthetic, or antibiotic prophylaxis
6. Known coagulopathy or current anticoagulant therapy where injection is contraindicated

7. Diagnosis of inflammatory arthropathy (e.g., rheumatoid arthritis) or other systemic inflammatory joint disease affecting the target joint
8. Pregnancy or breastfeeding
9. Inability to complete study procedures or follow-up assessments
10. Any medical, psychological, or social condition which, in the opinion of the investigator, would make participation unsuitable or place the participant at undue risk
11. Only participants with capacity to provide informed consent will be included
12. Individuals lacking capacity to consent will not be recruited

Date of first enrolment

01/12/2026

Date of final enrolment

01/09/2028

Locations

Countries of recruitment

United Kingdom

England

Scotland

Wales

Study participating centre

University Hospital Southampton

Southampton University Hospital

Tremona Road

Southampton

England

SO16 6YD

Sponsor information

Organisation

University Hospital Southampton NHS Foundation Trust

ROR

<https://ror.org/0485axj58>

Funder(s)

Funder type

Funder Name

University Hospital Southampton NHS Foundation Trust

Alternative Name(s)

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.0	05/05/2026	07/05/2026	No	Yes