

Patient Participation Invite Letter 05.05.26

Version 1.0

Re: Your Arthrosamid® injection for your joint osteoarthritis - Your Help with an Important Follow-Up Study

Dear [insert name],

An Invitation

As a patient who had opted to have Arthrosamid® injection to treat your joint osteoarthritis (OA) as part of this study we would like to assess how effective this injection has been for you as a treatment for OA particularly when compared to other methods of treatment such as joint replacement surgery or corticosteroid injections. Participation in this study is entirely voluntary and you can change your mind about participating at any time.

Study Aims - Why Are We Doing this Study?

This study aims to assess the efficacy of intra-articular polyacrylamide hydrogel (Arthrosamid®) as a non-operative management for patients suffering from synovial joint osteoarthritis who are candidates for joint replacement surgery or corticosteroid injections. We are aiming to assess the efficacy of the intra-articular polyacrylamide hydrogel using patient reported outcome measures (PROMS) collected from participants up to two years following administration of the injection and complications from this intervention to determine the efficacy.

Study Name - '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'.

All research in the UK is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and approved by _____ Research Ethics Committee.

Study Details - What We Would Like You to Do

You may have previously been sent online questionnaires to complete about your condition, these are called 'outcome scores'. We would like you to complete outcome scores over

various time points over the next 2 years at the following intervals (6 months, 1 year and 2 years).

Consent to Participate and to Contact You

The study must adhere to UK data protection laws, so we need your consent for a few distinct but related things, so we can conduct the study:

1. Consent to join this important study that will help others
2. Consent to contact you by the research team by email and / or telephone
3. Consent to the publication and dissemination of the anonymised data

If you choose to participate in the study, it will involve the following:

- **Completing a simple online questionnaire over a 2 year period** - this allows us to analyse the success of your injection and whether you have experienced any issues following this. If it is easier to provide this information over the telephone, this can be arranged by the research team.

Why should you take part?

This study will provide valuable information to both surgeons and patients about the long term outcomes of polyacrylamide hydrogel (**Arthrosamid®**) something which will be invaluable to the medical scientific literature. Arthrosamid is a **gel-like injection** that is placed directly into your knee joint. It's made mostly of water with a special soft plastic (hydrogel) that stays in the joint instead of just numbing pain for a short time, Arthrosamid **Cushions the joint** and helps it move more smoothly, **Supports the joint lining**, which may reduce irritation and stays in place for a long time, so it can provide **lasting relief**

Future patients will benefit from better data about their options and surgeons will be able to ensure they offer their patients treatment options backed up by high quality evidence. Depending on the outcomes, it may reduce the number of patients who have to undergo major joint-replacing surgery. Currently, this is only licensed to be used in the knee however, this study aims to explore its affects in other similar joints such as the ankle.

Risks of the Study to You

Side effects of Arthrosamid®:

If you take part in this study you will have had polyacrylamide hydrogel (**Arthrosamid®**) which was approved by the medication safety governing body in the UK, MHRA in 2021 for use in the knee. Like all medical devices, it has risks associated with it.

Post-injection flare: Some people (around 20–30%) may experience mild pain for a few days after the injection, known as a post-injection flare. This usually settles with rest and simple over-the-counter pain relief. A much smaller number of patients may find the discomfort lasts for several weeks.

Infection:

Infection risk is reduced by taking prophylactic antibiotics (as we have discussed earlier). However, very rarely (approximately 1:50,000 injections) patients may get an infection in the area of the injection. An aseptic non touch technique (ANTT) is also adopted when administering the medication.

It is extremely rare to have an allergic reaction to Arthrosamid® or local anaesthetic (1:50,000). This would usually happen within the first few minutes of an injection and requires immediate medical attention. Very rarely the allergic reaction can be delayed.

Bleeding or bruising may also occur.

There is also the possibility that the treatment will not work. Local anaesthetic has a number of side-effects associated with it but a thorough history taken in advance helps to reduce the risk of intolerance and anaphylaxis.

Your data:

Your data will be stored securely, anonymised and only accessed by the research team for analysis. Once we have analysed the data, we aim to publish the findings in medical journals and present the key findings at academic conferences, which may include both in-person and virtual events. All of the data published and presented will be completely anonymised and you will not be identified as having been involved in the study, nor will you be identifiable from any of the data presented.

Withdrawing from the Study

You may withdraw from participation in the study at any time. Should you wish to do this, please email the research team on _____. If a publication from study has been submitted to a scientific journal (using your anonymised data), we won't be able to remove your data from the publication. However, any future publications will not have your data in it.

If you choose to withdraw, your data will be removed from the study. Any follow-up care you may need will not be in any way affected by your decision to withdraw from this study.

Other Studies

The research team may wish to contact you about further research on Arthrosamid®. For example, by asking you a different set of questions not asked in this study. Please let us know if you would be happy for us to contact you for this in the future. You don't have to decide now, and any decision you do make you can change later.

Further Information

If you have any questions or wish for further information about the study - please contact the research team at _____

If you are happy to proceed with participation in this study, we would be grateful if you could complete the electronic consent form (**LINK to consent Google form**) by no later than **[insert date here]**.

We look forward to hearing from you.

Yours sincerely,

Arthrosamid® Study Research Team
Chief Investigator: Mr Togay Koç