

Professor M. A. Imam
MD, D.SportMed, PhD, FRCS (Tr and Orth)
Subspecialist in Upper limb and Complex trauma reconstruction
Tel: 020 3384 5588
info@thearmdoc.co.uk
www.thearmdoc.co.uk

Pre-Administration Patient Information

Example Consent Form

ARTHROSAMID

The purpose of this document is to provide written information regarding the risks, benefits and alternatives of/to Arthrosamid injections for knee Osteoarthritis. This is supplementary to the discussion you have had with the doctor. It is important you fully understand this information so please read this document carefully.

WHAT IS A KNEE INJECTION?

Knee injections are often recommended for the treatment of pain and inflammation in and around the knee joint.

PROPOSED INTERVENTION

Arthrosamid is hydrogel injection administered by ultrasound guidance for symptomatic knee osteoarthritis. The hydrogel itself does not degrade and therefore it provides long-lasting relief, improving your quality of life. In clinical trials, patients reported a significant reduction in their pain symptoms by week 4 after their injection and, unlike other injectable treatments, the level of reduction was maintained at the 3 year follow up period.

DISCLOSURE

Before undergoing one of these procedures, understanding the associated risks is essential. No procedure is risk-free. The following risks are well recognised, but there may also be risks not included in this list that are unforeseen by the doctors.

This is a new treatment with early promising results. Arthrosamid is a device and not a medicine. It has received the appropriate CE marking.

As this procedure has not yet been fully assessed by the National Institute for Health and Care Excellence (NICE). Your surgical team will therefore ask you to complete a short questionnaire prior to and following your treatment to monitor your response.

INTENDED BENEFITS:

Arthrosamid® is approved for the symptomatic treatment of knee osteoarthritis so any patient with this condition may be suitable. Over the last 13 years many patients have

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benefitted from treatment with the hydrogel in Arthrosamid®. Typical Symptoms include pain, stiffness, swelling and physical function.

ALTERNATIVE TREATMENT OPTIONS:

Given that this is a novel treatment we wish to confirm that all appropriate treatments have been explored. These may include:

- Physiotherapy course
- Activity modification
- Weight management
- Analgesia
- Steroid/hyaluronic acid injection/platelet rich plasma (PRP) injection
- Mechanical aids such as bracing

Surgery may be an alternative, and may remain a possible option should the hydrogel injection not help.

NO INTERVENTION:

Not having the injection is a reasonable option, and if you are in any doubt then you are advised not undergo this treatment.

BEFORE THE PROCEDURE:

As Arthrosamid is a device and not a medicine and given the injection is permanent it is therefore important that 1-2 hours before the injection oral antibiotics must be taken to reduce the risk of developing an infection.

- Please inform the doctor of any known allergies;
- Please bring a list of your current medications with you;
- You should take your medication as normal. If you are taking anticoagulant medication you may be given special instructions;
- You may eat and drink as normal;
- Your doctor will discuss the procedure with you and ask you to sign a consent form;
- If there is any possibility that you may be pregnant, please inform the doctor or nurse.

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THE PROCEDURE:

- The procedure is carried out in one of the clinic treatment rooms;
- You will be asked to sit or lie on a hospital couch;
- The doctor will clean your skin with an antiseptic solution which may feel cold;
- A local anaesthetic will be injected with a fine needle. This may sting initially before the skin goes numb.
- If a small dressing has been placed over the needle insertion site. This can be removed in the evening.

CAN EVERYONE HAVE THIS TREATMENT?

Arthrosamid® may not be suitable for everyone. Your doctor is the best person to advise you, but situations where you should not use Arthrosamid® (contraindications) include:

- You have a temperature
- If you have haemophilia or take anticoagulant treatment
- If you have had a knee arthroscopy within the past 6 months
- Very unstable joint
- If you have active skin disease or infection is present at or near the injection site
- If your joint is infected or severely inflamed
- If a degradable intra-articular injectable such as hyaluronic acid is present, it must be expected to be absorbed according to manufacturer's information for the specific product, before injection with Arthrosamid®
- If you have previously received treatment with a different non-absorbable injectable/implant
- If you have received a knee alloplasty or has any foreign material in the knee

Additionally, your doctor may advise you not to have treatment with Arthrosamid® if your diabetes is poorly controlled, you are having major dental work, or you have been diagnosed with an autoimmune disorder, (such as Multiple Sclerosis, Addison's, or Coeliac disease). If you are under 18, pregnant, breastfeeding, or have a foreign body in your knee, your doctor may advise against the injection.

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PLEASE TELL THE DOCTOR IF YOU HAVE ANY ALLERGIES OR HAVE EVER HAD A REACTION TO A MEDICATION.

RISKS:

No procedure is risk free. Sterile techniques are always used, which helps to reduce this risk.

Summary Key risks include:

- Non-efficacy (the treatment may not work)
- Short lived efficacy (the treatment may work for a limited time)
- Joint infection
- Allergic reaction to Antibiotics, local anaesthetic, preservatives or to the hydrogel itself.
- Post injection flare: Injection-related mild to moderate pain and/or mild swelling during the first few days to weeks following the injection may occur
- Swelling of Baker's cyst may also occur
- Worsening of symptoms
- Bleeding/bruising

Please feel free to discuss these with your treating doctor.

AFTER THE PROCEDURE:

You should avoid any strenuous weight-bearing activities (e.g. running, tennis or long walks) during the first few days after your injection. Your doctor will be able to advise you on how to slowly introduce more activity.

- After the procedure you may need to rest for 20-30 minutes;
- You are advised to avoid driving after the injection, on the day of treatment.
- The injected knee can feel uncomfortable once the local anaesthetic has worn off.
- Take your regular medication and pain killers as normal.
- If after the injection your knee becomes red, hot, swollen or more painful please call the clinic.

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Patients can start to notice a gradual improvement in symptoms after about 10 days. However the majority of patients take longer to see the effect of the treatment. Pain levels and function improve for up to 6 months following the treatment and should last multiple years.

Please note if in the future you require a major surgical or dental procedure, you should tell your treating physician that you have an Arthrosamid® implant in your knee to ensure an accurate medical assessment.

FURTHER INFORMATION:

If you have any questions or would like further information, please contact the clinic on xxxxxxxxxxxxxxxx.

CONFIRMATION OF REFLECTION

It is important before undergoing any non-emergency treatment that you have time to:

- Reflect upon the information provided
- Consider other treatment options
- Speak to friends and family
- Ask any follow up questions you may have

HOW EFFECTIVE IS THE TREATMENT:

Like most medical treatments every patient responds slightly differently. Younger patients with less severe arthritis seem to respond better to the injection. Over all 73% of patients felt that a single injection of Arthrosamid significantly improved their symptoms. This number is slightly higher in the under 70s (80%) and slightly lower in the over 70s (63%).

FOLLOW UP

We are very keen to monitor your progress, and understand how you respond to the treatment. For this reason, we will contact you at time points after the injection to find out how you are doing. This may involve follow up appointments, video consultation of possible telephone assessments, and on line questionnaires. There is no obligation to take part, but we would encourage your participation.



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Patient Name:

Date of Birth:

Diagnosis:

Type of injection: Arthrosamid

Patient information leaflet given and read by patient YES/NO

CONSENT:

My consent and authorization for this elective procedure is strictly voluntary. By signing this informed consent form, I hereby grant authority to the practitioner to perform injections to area(s) discussed during our consultation. I have read this informed consent and certify I understand its contents in full. All of my questions have been answered to my satisfaction and I consent to the terms of this agreement. I agree to adhere to all safety precautions and instructions after the treatment. I have been instructed in and understand post treatment instructions. I understand and acknowledge that no guarantee has been given or implied by anyone as to the results that may be obtained by this treatment. I also understand this procedure is "elective" and not covered by insurance and that payment is my responsibility. Payment is expected in full at the time of treatment and is non-refundable

I have been informed of the possibility of complications as detailed above. If you are happy to proceed and have no further questions please sign and date below

I understand that any procedure in addition to those described on the form will only be carried out if its necessary to save my life or prevent serious harm to my health.

Patient name

Date of birth

Signature & Date

Clinician name

Signature & Date

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Response rate with Arthrosamid[®]7,23,24

A randomised study of one-year performance of polyacrylamide hydrogel (iPAAG) vs. hyaluronic acid.²³

80% response rate with the under 70 year olds.⁷

