NCT Number: NCT03431584

INFORMATION SHEET

Effects on pain of infiltration with hyaluronic acid and corticosteroids versus corticosteroids alone in rhizarthrosis.

RHIZ'ART

Coordinating investigator	**Sponsor**
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Dear Sir or Madam

You have been invited to take part in a clinical study called **RHIZ'ART**. The CHD Vendée de la Roche sur Yon is the promoter of this study, and is responsible for its organization.
Before you decide to take part in this study, it's important for you to understand its purpose and implications. Please take the time to read the following information carefully, and discuss it with your family and friends. If there are any points that are unclear, or if you need further information, don't hesitate to discuss them with your doctor. You can take as much time as you need to decide whether or not to take part in the study.

If you decide to take part in this research, you will be asked to sign a consent form. This signature will confirm that you agree to take part in this study.

1- PURPOSE OF THE STUDY

You are currently being treated for osteoarthritis of the thumb.
The usual treatment for this condition combines non-medicinal measures, such as relative rest of the joint, rest orthosis, icing, etc., with medicinal measures such as analgesics and non-steroidal anti-inflammatory drugs.
You've already been offered several treatments (analgesics, anti-inflammatories, icing, etc.) but your pain persists, so you're going to receive an infiltration to try and relieve it.

These infiltrations (of corticoids or hyaluronic acid) are reputed to be effective and used regularly.
However, the two types of infiltration have been compared with each other, and both have been shown to be effective in reducing pain and improving function.
Interestingly, one study demonstrated the benefits of combining them in knee osteoarthritis, with the combination being more effective than hyaluronic acid alone in terms of pain, while the improvement in function did not differ between the two groups.
To date, no study has tested the benefits of combining corticosteroids and hyaluronic acid in osteoarthritis of the thumb. In view of this information, we propose to carry out the **RHIZ'ART** study.

The aim of this study is to compare the pain experienced by patients 3 months after their infiltration, between those who received the combination of hyaluronic acid and corticosteroids and those who received the combination of corticosteroid and saline.

The corticosteroid used in this study was Diprostene®, an anti-inflammatory agent indicated for the treatment of relapsing osteoarthritis. The hyaluronic acid used is Sinovial mini®, indicated for pain or reduced mobility in osteoarthritic joints.

If you agree to take part in the study, you will be randomized to receive either corticosteroid and saline alone, or corticosteroid plus hyaluronic acid.

To ensure that the results are not distorted, the study is blinded, which means that you will not be aware of the group into which you have been drawn. Only the nurse who prepares the syringes and the doctor who performs the infiltration will be aware of the product infiltrated. Similarly, the person who comes to see you in order to record your pain (the aim of the study) will be different from the person who performed the infiltration, and this person will also be unaware of the product you received.
In both groups, patients will receive the same dose of corticosteroids. All patients will receive two products: either a syringe of corticosteroids and a syringe of hyaluronic acid, or a syringe of corticosteroids and a syringe of saline. Saline provides no therapeutic benefit, and is also known as a "placebo". It ensures that you won't be able to tell which group you've been drawn into, since you'll receive two injections regardless of which group you're in.

The study will involve 150 patients treated at the La Roche sur Yon, Nantes and Le Mans hospitals. The total duration of participation is one year for each patient, irrespective of the group drawn.

2- STUDY PROCEDURE

Participation involves a total of 6 visits during the course of your treatment:

- a so-called pre-inclusion visit, during which the doctor explains the project to you, checks that you meet the criteria for participation, your medical history, etc.
- a visit on the day of your infiltration
- then 4 follow-up visits: one at 1 month, 3 months, 6 months and 12 months post-infiltration.

Data will be collected at each visit:

- your pain level (pain at the time of infiltration, pain when pinching your thumb and index finger, etc.)
- your consumption of analgesics
- if necessary, the number of new infiltrations you have received
- the number of days off work
- any adverse events you may have experienced
- answers to a questionnaire on everyday activities that could be affected by your osteoarthritis (Cochin score)
- results of a hand mobility test (grip and opposition test using a dynamometer)
- a questionnaire on the overall evolution of your rhizarthrosis
- the need for a surgical procedure.

On the day of your infiltration, you'll also undergo an ultrasound scan, which will be repeated 3 months after your infiltration to check for any changes.

You will also be asked to fill in a patient diary every week for the first 3 months after the infiltration. This diary will be used to record your pain and any adverse events (whether possibly related to the infiltration or not).

3- CONSTRAINTS AND POTENTIAL RISKS OF THE STUDY

The main constraints of the study concern the completion of the patient diary during the 3 months following your infiltration, and your arrival at the hospital for the follow-up visits scheduled as part of the protocol.

The risks involved are benign, temporary and already known, since the products tested have already had their marketing authorization for many years, and will be used in their intended indication and according to good clinical practice.

4- POTENTIAL BENEFITS OF THE STUDY

We assume that the analgesic action of the product(s) proposed for this condition will have a beneficial effect on your pain.
We can also envisage a collective benefit from this research by optimizing the management of patients like you who suffer from osteoarthritis of the thumb.

5- VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary.

You are free to refuse to take part, or to end your participation at any time, without incurring any liability or prejudice, and without any consequences for the quality of the care you receive.
In this case, you must inform the investigating physician of your decision.
If you withdraw your consent, your personal data will be processed for the purpose of analyzing the study, unless you object in writing.

During the course of the study, you will be informed by your investigating physician if new facts affect your willingness to participate in the study.

The Health Authorities, your investigating physician or the sponsor may decide to terminate your participation in the study at any time without your prior consent. If this should happen, you will be informed and the reasons will be explained to you.

6- OBTAINING FURTHER INFORMATION

If you wish, Doctor [.....], who can be reached on the following telephone number
.....], will be happy to answer any questions you may have about the **RHIZ'ART** study.

At the end of the study, and at your request, you may be informed of the overall results of the research by your investigating physician.

7- CONFIDENTIALITY AND USE OF MEDICAL DATA

As part of the biomedical research in which the CHD Vendée proposes that you participate, your personal data will be processed to enable the results of the research to be analyzed in relation to the objective of the research, which has been presented to you.

To this end, the medical data collected, including any questionnaires and data relating to your lifestyle, will be transmitted to the Sponsor of the research or to persons acting on its behalf, in France or abroad. This data will be identified by a code number and/or your initials (first letter of your surname and first letter of your first name).

The staff involved in the study are bound by professional secrecy, as is your treating physician. This data may also be transmitted, under conditions ensuring confidentiality, to French or foreign health authorities, or to other entities of the CHD Vendée de la Roche sur Yon.

In accordance with the French Data Protection Act of January 6, 1978, you have the right to access and rectify your personal data. You also have the right to object to the transmission of data covered by professional secrecy that may be used in this research and processed.
You also have the right to access all your medical data, either directly or through a doctor of your choice, in accordance with article L 1111-7 of the French Public Health Code.
These rights may be exercised with the doctor who is treating you as part of the research and who is aware of your identity.

8- INSURANCE

An insurance policy No. 131.155 has been taken out by the trial sponsor with the SHAM insurance company to cover the risks associated with this research. This insurance covers the sponsor's liability as promoter of biomedical research, and that of any other parties involved, in accordance with article L 1121-7 of the French Public Health Code.

9- FAVORABLE OPINION OF THE CPP

In accordance with French law no. 2004-806 of August 9, 2004 on public health policy, the Comité de Protection des Personnes Ile de France III has studied this research project and issued a favorable opinion on [.....] .

10- ANSM AUTHORIZATION

In accordance with French law no. 2004-806 of August 9, 2004 on public health policy, the ANSM has studied this research project and issued an authorization to carry it out on [.....]

If you agree to take part in this study, please complete and sign the consent form. You will keep this information note.

CONSENT FORM

Effects on pain of infiltration with a combination of hyaluronic acid and corticosteroids versus corticosteroids alone in rhizarthrosis.

RHIZ'ART

Sponsor: Centre Hospitalier Départemental Vendée - Unité de Recherche Clinique **Address:** Boulevard Stéphane Moreau - 85925 La Roche sur Yon **Telephone:** 02 51 44 65 72 **Fax:** 02 51 44 62 98

Dr/Pr. ..... of the CH .... Rheumatology Department **invited me to take part in the RHIZ'ART clinical study.**

The investigating physician explained the study to me. I have read and understood the information leaflet, a copy of which I have obtained. The investigating physician has answered all my questions about the study. I may, at any time, request further information from the above-mentioned doctor who proposed my participation in the study.

I have had the necessary time to consider my involvement in this study, and I am aware that my participation is entirely voluntary and that this study will not generate any additional costs for me.

I am free to refuse to take part in the study without incurring any liability or prejudice as a result, and without any consequences for the quality of care provided to you.
I may decide to leave the study at any time without giving any reason and without any consequences for the quality of my care.

I understand that the data collected in the course of the research will be kept confidential. It may only be consulted by persons subject to professional secrecy belonging to the investigating physician's team, mandated by the sponsor or representatives of the health authorities.

I agree to the processing of my personal data in accordance with the French Data Protection Act. I have been informed of my right of access, rectification and opposition to the transmission of data covered by professional secrecy that may be used in this research and processed. These rights may be exercised with the doctor who is treating you as part of the research and who is aware of your identity.

I certify that I am affiliated to the Social Security system.

I have been informed that, in accordance with the regulations governing clinical trials, the CPP Ile de France III has issued a favorable opinion for the performance of this research on ..... and that the ANSM has also authorized it on .....

My consent does not relieve the research organizers of their responsibilities. I retain all my rights guaranteed by law.

Signed in two original copies

....., ...

Signature investigator:

Patient's surname/first name: .....

Patient's signature :