HYMN Protocol

- Minimal Risk Minimal Constraint Interventional Research -

Registration number: 2019-A03180-57

Ref : CHD 202-19

"Interest of hypnosis on pain management during an ultrasound guided infiltration of the hand

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SIGNATURE PAGE

SIGNATURE OF THE PROMOTER

The sponsor undertakes to carry out this study in accordance with all legislative and regulatory provisions that may apply to the research and in accordance with the protocol.		
Name and function of the signing representative : **Mr Francis SAINT-HUBERT** **General Director of the CHD Vendée**	**Date :**	**Signature :**

SIGNATURE OF INVESTIGATOR S

I have read all the pages of the protocol of the clinical trial for which the CHD Vendée is the sponsor. I confirm that it contains all the information necessary for the conduct of the trial. I undertake to carry out the trial in accordance with the protocol and the terms and conditions defined therein. I undertake to carry out the trial in compliance with :

- the principles of the "Declaration of Helsinki",
- the international (ICH) and French rules and recommendations of good clinical practice (rules of good clinical practice for interventional research involving medicines for human use)
- European and/or national legislation and regulations on clinical trials,

I also undertake that the investigators and other qualified members of my team will have access to this protocol and to the documents relating to the conduct of the trial to enable them to work in accordance with the provisions of these documents.

	Name :	**Date :**	**Signature :**
Head of Research	**Adeline TROJET-BOSSARD**		

LIST OF ABBREVIATIONS

ARC	Clinical Research Associate (monitor)
GCP	Good Clinical Practice
PPC	Committee for the Protection of Individuals
CNIL	Commission Nationale de l'Informatique et des Libertés
eCRF	Electronic Case Report Form
ICH	International Conference on Harmonization
MR	CNIL Reference Methodology
RIRCM	Minimal Risk and Minimal Constraint Intervention Research

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1. RATIONALE FOR THE STUDY

1.1. POSITIONING OF THE RESEARCH

Echo guided hand infiltration is usually prescribed to relieve chronic pain. According to *the International Association for the Study Pain*, pain is "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms suggestive of such damage [1]".

Echo guided infiltration is a relatively common procedure and is generally considered to be locally painful. This pain induced by the treatment, leads to a strong apprehension among patients who have to undergo this procedure.

In order to reduce the stress of the patients, several approaches were put in place, namely: explanation of the procedure, setting up a relaxed atmosphere (notably through discussion). All these elements constitute a form of hypnosis known as conversational. Nevertheless, according to our observations, it remains insufficient for the management of the pain of infiltration.

The practice of hypnosis to improve patient comfort during care has gradually appeared in hospital departments. It is used in surgery, particularly for dressings for burn victims, and increasingly in medicine [2]. Jean-Marc Benhaiem, in 2003, indicated that "therapeutic hypnosis is a relational experience bringing into play physiological and psychological mechanisms allowing the individual to better live, to attenuate or to eliminate an acute or chronic painful pathology [3]. The hypnotic state would allow to modulate feelings, in particular emotions such as pain or anxiety [4 & 5].

There are several forms of hypnosis, Ericksonian hypnosis lets the subject solve his problem without direct intervention dictating the solution. It is only necessary to guide him, to choose the ideas, the images... that he likes and that suit him.
This decreases attention, the relationship to reality, spontaneous mental activity and the perception of time, but allows the refocusing of attention towards bodily sensations and mental contents proposed by the induction, as well as concentration and adherence to the imagery.
Erickson said: "go and find your own ways to change".
Ericksonian hypnosis is essentially therapeutic, it is not spectacular. This method can be integrated into the treatment process without significantly increasing the time of the procedure.

Among the different conversational hypnosis techniques that exist, there is the magic pen where the patient is made to choose a pencil, the liquid is described, the colour, the smell... and the pencil is put on the hand, the liquid is allowed to imagine that it is put in the hand and it is spread "like sunshine", the liquid is made to feel by rubbing the hand, which creates a protection.

There is another technique which takes the patient to the place they want with a formal, nonconversational induction, often questioning, but lasting more than thirty minutes.

Each way brings the patient into a similar altered state of consciousness. Everything is improvised, it depends on the individual.

Within the framework of the Hymn project, the "magic glove" technique was chosen because it seems to us to be the simplest to carry out with the patient and is consistent with the hand infiltration technique. This technique consists of creating an imaginary glove, invented by the

patient himself, around his hand which will "anaesthetise" the pain. The patient's hand is cataleptic or levitated, and is then connected to what is pleasant, "luminous".

We wish to evaluate here the interest of hypnosis on the pain felt by the patient during the realization of an echo-guided infiltration of the hand, one of the most painful extremities during infiltrations.

1.2. BENEFITS AND RISKS FOR RESEARCH PARTICIPANTS

1.2.1. Benefits

1.2.1.1. Individual benefit

The expected benefit of a hypnosis session prior to an ultrasound-guided hand infiltration is a reduction in the sensation of pain at the time of the infiltration.

This benefit will be objectively assessed by means of a pain assessment directly by the person using a pain scale (VAS)

1.2.1.2. Collective benefit

The use of hypnosis in the performance of painful treatments such as ultrasound-guided hand infiltration could optimise patient care.
This could also reduce the time of the procedure as patients will be more relaxed and the rheumatologist will be able to perform the procedure more accurately.

1.2.2. Risks

No excess risk is expected as a result of participation in the study.

1.2.2.1. Individual risk

- Related to the hypnosis procedure: no risk has been demonstrated for the practice of hypnosis [2]. No individual risk is expected for this study

1.2.2.2. Individual constraints

The constraints related to filling in the questionnaires are considered minimal. In the experimental group "Infiltration under ultrasound + Hypnosis", the consultation will be extended by about ten minutes compared to usual practice.

1.2.2.3. Collective risk

No collective risk is expected for this study. There are no changes in management outside of randomisation.

1.2.3. Benefit/risk balance

The person in charge of the research qualifies it as **interventional research with minimal risks and constraints**, because the hand infiltration technique and the drugs are used in common practice. It is not expected that there will be any excess risk in relation to these practices as a result of participation in the protocol.

The research does not focus on innovative or obsolete techniques or strategies.

The overall management of the patient will be the same as usual.

Consequently, the particular modalities of implementation in the research represent negligible constraints for the person who lends himself to the research. (Article R 1121-3 of the Public Health Code (CSP), decree n° 2006-477 of 26 April 2006)

The person in charge of the research will therefore, before any implementation of the research, submit the study protocol to a Committee for the Protection of Individuals in accordance with article L 1121-1 of the Public Health Code (CSP) as they result from laws n° 2004-806 of 9 August 2004 and n° 2006-450 of 18 April 2006 relating to public health policy, for a favourable opinion and confirmation of the qualification of the research.

2. OBJECTIVES AND JUDGING CRITERIA

2.1. OBJECTIVE AND PRIMARY ENDPOINT

2.1.1. Main objective

The main objective is to show that the practice of hypnosis makes it possible to reduce the pain felt by the patient during an ultrasound-guided infiltration procedure on the hand.

2.1.2. Primary endpoint

VAS pain at rest 5 minutes after the ultrasound-guided infiltration of the hand

2.2. OBJECTIVES AND SECONDARY ENDPOINTS

2.2.1. Secondary objective(s)

Assessment of patient anxiety 5 minutes after the procedure is performed

2.2.2. Secondary endpoint(s)

Spielberger Anxiety-Status Scale (STAI form Y-A) score experienced 5 minutes after infiltration

3. STUDY POPULATION

3.1. DESCRIPTION OF THE POPULATION

Number of patients to be randomised: 80 patients randomised (see § justification of the number of subjects).

This study is aimed at adult patients treated in the rheumatology department of the CHD Vendée for the first time for an ultrasound guided infiltration of the hand.

Recruitment will be carried out prospectively on arrival in the rheumatology department

4 to 6 new patients per month are treated by the CHD Vendée for a first hand infiltration under ultrasound.

The study plans to include 92 patients. However, the inclusion period will end when 80 patients are randomised.

3.2. INCLUSION CRITERIA

- Patient with an indication for a first hand infiltration under ultrasound
- Patient of legal age
- Patient with the ability to understand the protocol and who has given informed consent
- Patient with social security coverage

3.3. NON-INCLUSION CRITERIA

- Patient with a preventive pain patch on the area to be infiltrated
- Contraindication to infiltration (unbalanced diabetes, unbalanced hypertension, ongoing infections)
- Hearing impaired patient

- Patient under guardianship/guardianship
- Minor
- Pregnant woman
- Patient participating in another interventional research protocol
- Patient unable to follow the protocol, as judged by the investigator.

3.4. EXPECTED DURATION OF PARTICIPATION OF INDIVIDUALS AND A DESCRIPTION OF THE TIMING AND DURATION OF ALL TRIAL PERIODS

Inclusion period: 26 months
Duration of patient participation: 2 hours
Duration of the study: 26 months

4. DESIGN AND STUDY PROCESS

4.1. GENERAL RESEARCH METHODOLOGY

The research has the following characteristics:

- Type of research: Minimal Risk Minimal Constraint Interventional Research (MRIC) - Single-centre, controlled, randomised, open-label, superiority study.

4.2. CONDUCT OF THE STUDY AND TIMETABLE OF THE STUDY

1. Inclusion and Randomisation (D0)

[e]In order to ensure the feasibility of the study, patients scheduled for ultrasound-guided hand infiltration will be scheduled when two nurses, one of whom is trained in hypnosis, are present on the ward.

The inclusion consultation will check the inclusion and non-inclusion criteria. A presentation of the study will be made by one of the two nurses. Written information will be given to the eligible patient. The patient's oral, informed consent will then be collected.

Randomisation will be carried out during this consultation. Depending on the randomisation arm the patient will receive either :

- A single ultrasound-guided infiltration of the hand (standard arm)
- A single ultrasound-guided infiltration of the hand under hypnosis (experimental arm).

In this study, where the standard of care is "infiltration only", a placebo group is not planned. The aim of our study is to evaluate the contribution of hypnosis as a global approach to patient management.

Echo guided infiltration technique - Standard arm:

The patient will be installed in the usual way by the non-hypnosis trained nurse.

The rheumatologist will carry out the localisations under ultrasound. The nurse will then disinfect the patient's hand in 3 steps with an iodinated skin antiseptic. The infiltration will be carried out in a standardised way by a rheumatologist of the department.

Hypnosis-guided echo infiltration technique - Experimental arm:

Hypnosis will be started after the result of the randomisation, the patient will be taken care of by the nurse trained in hypnosis (see § 4.4 description of the method used).

When the patient is ready, just after the hypnosis session, the nurse will disinfect the patient's hand in 3 steps with an iodinated skin antiseptic and the rheumatologist will perform the infiltration in a standardised way.

In both groups, the Spielberger Anxiety-Trait Scale (STAI form Y-B) will be collected before the intervention and before hypnosis (experimental arm). This score will be used to characterise and describe patients' anxiety before the intervention.

In both groups, the Spielberger Anxiety-Status Scale (STAI form Y-A) will be performed 5 minutes after the infiltration procedure.

The pain VAS will be collected before the hypnosis intervention in order to characterise the pain related to the pathology.

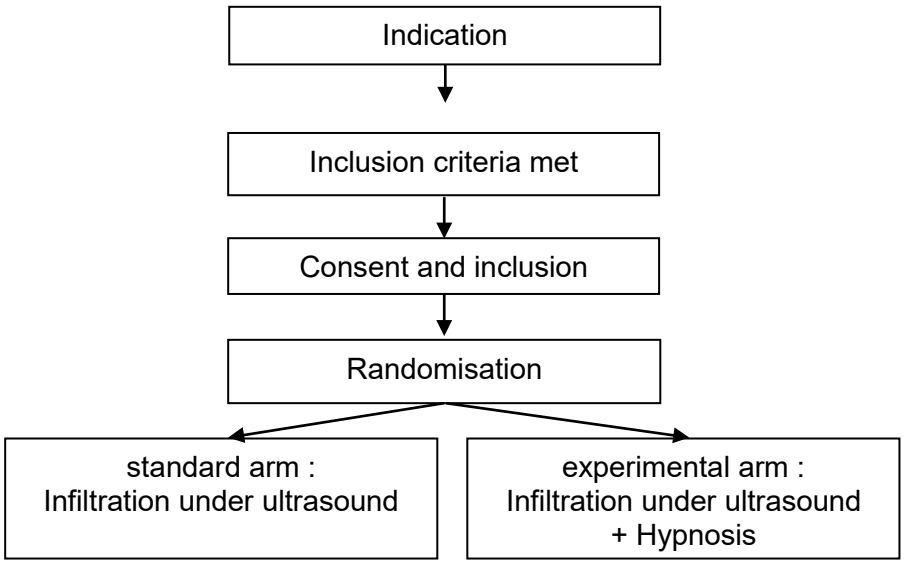
The pain VAS will then be collected 5 minutes after the infiltration procedure in order to characterise the pain linked to the infiltration procedure.

The use of analgesic treatments by the patient before the ultrasound guided infiltration will be collected.

TIMETABLE OF THE STUDY

Actions	J0 (Inclusion visit)	5 minutes after the action
Patient information	X	
Informed oral consent	X	
Randomisation	X	
Background	X	
Clinical examination	X	
Hypnosis	X	
Medical procedures: ultrasound-guided infiltration	X	
VAS for pathology-related pain	X	
EVA pain of the gesture		X
Anxiety-Trait Scale	X	
Anxiety-Status Scale		X
Analgesic treatments	X	

4.3. SCHEME OF THE STUDY



4.4. DESCRIPTION AND JUSTIFICATION OF THE METHOD STUDIED

The duration of the hypnosis session will be measured.
The hypnosis session consists of building a "magic glove" with the patient on the hand on which the infiltration will be performed.
The nurse sets up the patient and the rheumatologist uses the ultrasound machine to locate the hand.
The nurse, trained in hypnosis, starts the timer, takes the patient's hand in her hand and begins the hypnosis session. The principle is to get the patient to imagine a glove that they will create to put on their painful hand.
The nurse lets the patient choose the colour, material and asks how far the glove fits on the arm.
The nurse guides the patient to put the glove on each finger by touching the hand.
By suggestion, the nurse forms an anaesthetic area on the hand according to the patient's choice.
If the "protection" is not sufficient, the nurse adds a "strip" or "resin" to increase the anaesthetic.

A phenomenon of catalepsy or levitation of the hand is generated in the patient.

The "magic glove" technique is suitable for hand infiltration because a glove can be slipped onto a hand.

When the patient is ready, the nurse stops the timer and disinfects the patient's hand in 3 steps and the rheumatologist carries out the infiltration in a standardised manner.

4.5. DESCRIPTION OF THE EVALUATION AND THE DATA COLLECTED

- The Visual Analogue Scale (VAS) of pain is used to assess the progression of pain (Scott & Huskisson, 1976). It is rated from 0 to 10 on a ruler, and the patient must move the cursor on the side without graduation. The nurse records the intensity of the pain felt on the graduated side.

- The Spielberger Anxiety-State Scale is a way of finding out what the patient is feeling "right now, just at this moment". It consists of 20 items (10 items reversed). The scale assesses the intensity of what the patient is feeling. Each item is rated from 1 to 4, with 1 indicating the lowest degree of anxiety and 4 the highest.
  It is a questionnaire that takes an average of 5-10 minutes to complete. The sensitivity of the items to changes in anxiety in different anxiety-provoking situations has been demonstrated [6].

- The Spielberger Anxiety-Trait Scale captures what the patient "usually" feels. It consists of 20 items (9 items reversed). The scale assesses the frequency of what the patient feels. Each item is rated from 1 to 4, with 1 indicating the lowest degree of anxiety and 4 the highest. This questionnaire takes an average of 5 to 10 minutes to complete.

  Both questionnaires have been validated in French [6].

4.6. IDENTIFICATION OF ALL SOURCE DATA NOT IN THE MEDICAL RECORD

- EVA pain before the infiltration procedure and before hypnosis
- VAS pain 5 minutes after the infiltration procedure
- Anxiety-Treatment scale before the infiltration procedure and before hypnosis
- Anxiety-Status scale 5 minutes after the infiltration procedure

4.7. RULES FOR STOPPING A PERSON'S PARTICIPATION

4.7.1. Criteria for premature termination of a person's participation in research

A person's participation may be terminated prematurely for the following reasons:
- Withdrawal of consent by the patient
Subjects will be able to withdraw their consent and ask to leave the study at any time and for any reason.

4.7.2. Data collection schedule

In case of withdrawal of consent by the patient, and without prejudice to the patient's right, the data already collected will be analysed unless the patient objects.

No other examinations specifically foreseen by the protocol will be carried out and no data will be used according to the patient's wishes after withdrawal of consent.

The discharge of a patient from the study will not change the usual management of the patient's condition.

4.7.3. Discontinuation of part or all of the research by decision of the sponsor (excluding biostatistical considerations)

Part or all of the study may be stopped permanently or temporarily by decision of the ANSM, the CPP or the Study Sponsor.

In all cases :

- A written confirmation will be sent to the coordinating investigator of the study (specifying the reasons for premature termination).
- All patients in the study will be informed.

5. SAFETY ASSESSMENT

In the context of this Minimal Risk and Minimal Constraint Interventional Research (RIPH Category 2), the adverse event(s) (serious or not) do not have to be notified to the sponsor. Notification must be made within the framework of the vigilance set up in the context of care for the product or practice which is the subject of the research (pharmacovigilance for a drug, materiovigilance for a medical device, etc.) according to the regulations in force.

Only "new facts" and malfunctions that may interfere with the research must be transmitted to the sponsor without delay after becoming aware of them so that corrective measures can be put in place. For these malfunctions, the investigator can use the reporting form to the regulated system, made anonymous (patient inclusion number only).

A new fact is any new data that may lead to a reassessment of the benefit/risk ratio of the research or the product under investigation, to changes in the use of the product, in the conduct of the research, or in the documentation of the research, or to the suspension or discontinuation or modification of the research protocol or similar research.

The promoter shall inform the competent authority and the Committee for the Protection of Individuals without delay of the new facts and, where appropriate, of the measures taken, as from the day on which he becomes aware of them.

6. DATA MANAGEMENT AND STATISTICS

6.1. COLLECTION AND PROCESSING OF STUDY DATA

6.1.1. Data collection

One case report form (CRF/ eCRF) will be created per patient. All information required by the protocol should be provided in the CRF/eCRF. It should include the data needed to confirm compliance with the protocol and all data needed for statistical analysis; it should identify major deviations from the protocol.

The person(s) responsible for filling in the CRFs/eCRFs (investigator, CRA...) should be defined and is/are identified in the Centre's Delegation of Duties Form (kept in the investigator's folder).

6.1.2. Data coding

By signing the protocol, the principal investigator and all co-investigators agree to keep confidential the identity of the patients who participated in the study.

The transmission of a person's data for research purposes will therefore only be possible if a coding system is applied; the presentation of the research results must exclude any direct or indirect identification.

The identification of patients will be done according to the order of inclusion of patients by a number automatically assigned by the Clinsight software (eCRF) then completed by the initials of the patients (1st letter of the first name + 1st letter of the last name).

This code will be the only information that will appear on the eCRF notebook and will allow the eCRF to be linked to the patient afterwards.
The investigator is also required to code the patient data on any documents he/she may have in his/her possession (reports of imaging or biological examinations, etc.) which are attached to the eCRF.

A mapping table will be set up in the participating centre. This table will be kept in a secure place by the principal investigator of the centre and will contain the patient code and his or her personal data in order to be able to go back to the patient file in case of missing or erroneous data. No clinical data will be collected in these correspondence tables.

6.1.3. Data processing

The collection of clinical data will be based on the implementation of a database and the creation of data entry masks similar to the observation book in accordance with the protocol and regulations currently in force.

6.2. STATISTICS

Software

The analyses will be carried out using R software version 3.5.1

6.2.1. Description of the planned statistical methods, including the timing of planned interim analyses

All variables will be described globally and by group. The description will include the numbers and percentages of modalities for qualitative variables and the minimum, maximum, mean, standard deviation and median for quantitative variables.

VAS pain

The average pain felt during the procedure (collected 5 minutes after the procedure) will be estimated with a 95% confidence interval in the two groups. It will be compared using a Student's t test.

Anxiety

Anxiety after the procedure will be collected using the State-Anxiety questionnaire (STAI form YA). The total score of the questionnaire will be calculated in both groups. The mean will be presented with a 95% confidence interval and compared using a Student's t test.

6.2.2. Statistical justification of the number of inclusions

Currently, there is no data in the literature on the pain experience during ultrasound-guided infiltration of the hand. It has been shown that a decrease of 1.1 on the VAS is clinically significant in patients with rheumatoid arthritis (Wolfe et al. 2007).

We hypothesise that the hypnosis session may reduce the pain experienced during the procedure by 2 points. According to data from a study carried out in the department on patients for whom an infiltration of the thumb is indicated, we have retained a standard deviation of 3 for the pain felt during the infiltration procedure. Based on these assumptions and setting an alpha risk of 5% and

a power of 80%, a total of 74 patients should be randomised. In order to guarantee the power of the study, an additional 5% of patients will be randomised, i.e. 80 patients in total.

6.2.3. Expected level of statistical significance

The alpha risk is set at 5%.

6.2.4. Statistical criteria for stopping the research

NA

6.2.5. Method of accounting for missing, unused or invalid data

All missing data and the reason for it will be described in each group.

For the analysis of the primary outcome, a multiple imputation method will be applied.

6.2.6. Managing changes to the original strategy analysis plan

NA

6.2.7. Selection of persons to be included in the analyses

The main analysis will be performed on the Intent-to-Treat (ITT) population, i.e. on all randomised patients.

A complementary analysis will be performed on the Per Protocol (PP) population including the randomised patients for whom no major protocol deviations have been identified.
A data review meeting will be held to review and define the major criterion or not for each of the deviations.

6.2.8. Randomisation

Randomisation will not be stratified.

It will be carried out in a 1:1 ratio and will be done in blocks.

Randomisation will be carried out in Ennov Clinical by connecting to the website: https://www.dirc-hugo-online.org/csonline/. The connection will be made through a login, a password and a study number, delivered by the data manager of the Research Unit of the La Roche sur Yon Hospital. The following information must be filled in:

-First initial of the name,

-First initial of the first name,

-Month and Year of birth,

Compliance with inclusion and non-inclusion criteria (yes/no),

Randomisation will be carried out by the investigator after confirmation of the possibility of inclusion in the study. The inclusion number will be assigned automatically during randomisation. A confirmation email will be sent to the person who performed the randomisation and to all persons involved.

The randomisation list will be carried out by the statistician of the Research Unit of the CHD of La Roche sur Yon. An explanatory guide to randomisation will be available online in Ennov Clinical.

7. ADMINISTRATIVE AND REGULATORY ASPECTS

7.1. RIGHT OF ACCESS TO SOURCE DATA AND DOCUMENTS

In accordance with GCP :

- The sponsor is responsible for obtaining the agreement of all parties involved in the research to ensure direct access to all research sites, source data and reports for quality control and audit purposes by the sponsor,
- The investigators will make available to the persons in charge of monitoring, quality control or auditing the research, the documents and individual data strictly necessary for this control, in accordance with the legislative and regulatory provisions in force (articles L.1121-3 and R.5121-13 of the Public Health Code).

Source documents, defined as any original document or object that can be used to prove the existence or accuracy of a data or fact recorded during the clinical study, should be kept for 15 years by the investigator or by the hospital in the case of a hospital medical record.

7.2. DATA PRIVACY

Persons with direct access shall take all necessary precautions to ensure the confidentiality of information relating to the persons who have access, in particular as regards their identity and the results obtained.

These persons, as well as the investigators themselves, are subject to professional secrecy (according to the conditions defined by articles 226-13 and 226-14 of the penal code).

During or after the research, the data collected on the subjects and transmitted by the participants will be made anonymous.

Under no circumstances should the names of the persons concerned or their addresses appear in clear text.

Only the first letter of the subject's name and the first letter of the subject's first name will be recorded, along with a study-specific code number indicating the order of inclusion of the subjects.

7.3. MONITORING OF THE TRIAL

Monitoring will be carried out by the Promotion Department of the Research Directorate. A Clinical Research Associate (CRA) will regularly visit the investigator site to check the quality of the data reported in the observation books.

The monitoring plan is defined in consultation between the research team and the responsible institution according to the objectives of the study.

The protocol has been classified according to the estimated level of risk to the patient undergoing the research. It will be monitored as follows:

Risk A: low or negligible foreseeable risk

On-site monitoring visits will be organised after an appointment with the investigator. CRAs should be given access to each site:

- the data collection books of the patients included,
- patients' medical and nursing records, - the investigator's binder.

7.4. INSPECTION / AUDIT

In the context of this study, an inspection or audit may take place. The sponsor and/or the participating centre must be able to give access to the data to the inspectors or auditors.

7.5. DECLARATION TO THE COMPETENT AUTHORITIES

The sponsor undertakes to submit the study project for prior authorisation by a Personal Protection Committee (CPP). The information communicated concerns, on the one hand, the modalities and nature of the research and, on the other hand, the guarantees provided for the patients participating in this trial.

This protocol will also be reported to the ANSM.

7.6. AMENDMENTS TO THE PROTOCOL

Requests for substantial modifications will be sent by the sponsor to the CPP concerned for its opinion and to the ANSM for information in accordance with the law in force and its implementing decrees.

An updated dated version of the amended protocol will be required.
The patient information and consent forms will need to be amended if necessary.

7.7. COMPUTERISED DATA AND SUBMISSION TO THE CNIL

The data collected in this study are for scientific research purposes, for the public good.

This study falls within the scope of the "Reference Methodology" MR-001 registered, for the CHD Vendée, under n°2060482 v 0 for the following reasons

- Collection of health data for research purposes
- Obtaining the opinion of a CPP to start the research
- Use of anonymised data
- Individual information of data subjects
- Access to data only by professionals (health and sponsor) involved in the study.

The fact that this study falls within the scope of MR001 and the reasons for this will be notified in the sponsor's treatment register.

7.8. PATIENT INFORMATION

7.8.1. Informed consent oral

The investigator undertakes to obtain the free, informed and express consent of the patient, obtained orally, after having given him/her information on the protocol (information note and consent form in the appendix). The information will be given to the patient before the infiltration planned as part of his or her treatment. He will be given a copy of the information note and an oral consent form. The person can only be included in the study after having read the information note and given oral consent after having had, if necessary, time to reflect. The reflection time will be a few minutes.

The patient's information and consent to participate in the research should be recorded in the patient's medical record.

A copy of the information note and the consent form signed by the investigator will be given to the patient, the investigator will keep the original. A copy will be placed at the end of the study in a sealed tamper-proof envelope containing all the consent forms, which will be archived by the sponsor.

7.9. FINANCING AND INSURANCE

The promoter finances the study and takes out an insurance policy to cover the financial consequences of its civil liability, in accordance with the regulations.

7.10. RULES ON PUBLICATION

The study will be registered on an open access website (Clinical trial) before the first patient is included in the study.

Scientific papers and reports related to this study will be produced under the responsibility of the study coordinator with the agreement of the principal investigators of the participating centres.

The coordinating investigator establishes the list of authors.
A professional attached to the CHD Vendée at the time of publication will necessarily appear in the ranks of the first or last author.

The rules for publication will follow international recommendations (N Engl J Med, 1997; 336:309-315).

A copy of the publication will be given to the CHD Vendée promoter of the study, which will necessarily be cited.

7.11. ARCHIVING OF SOURCE DATA

The investigator should keep all information about the study for at least 15 years after the end of the study.
At the end of the study, the investigator will receive a copy of each patient's data from his centre sent by the sponsor.

No removal or destruction can be carried out without the agreement of the Promoter. At the end of the 15 years, the Promoter will be consulted for destruction. All data, documents and reports may be subject to audit or inspection.

8. BIBLIOGRAPHIC REFERENCES

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[5] Rainville P, Hofbauer RK, Bushnell MC. (2002). Hypnosis modulates activity in brainstructures involved in the regulation of consciousness. *Journal of Cognitive Neuroscience*, 14(6), 887-901.

[6] Bouchard, S., Gauthier, J., Thibodeau, C., & Ivers, H. (1999). The Situational Anxiety and Anxiety Trait Inventory Form "Y" in a population of college students, *Canadian Journal of Psycho-Education, 28*(2), 279-288.

9. Appendix

Echelle d'Anxiété-Trait de Spielberger

Questionnaire d'anxiété générale de Spielberger

Instruction :
Ci-après figurent un certain nombre de déclarations que les gens utilisent souvent pour se décrire. Lisez chacun des énoncés et cochez dans le case appropriée de droite ce qui convient le mieux à la façon dont vous vous sentez en général. Il n'existe ni bonnes ni mauvaises réponses. Ne passez pas trop de temps sur chacun des points, mais donnez la réponse qui semble décrire le mieux ce que vous ressentez généralement. Répondez à toutes les questions et ne cochez qu'une case pour chacune d'entre elles.

	Activités	Etat			
1.	Je me sens dans de bonnes dispositions	☐ Presque jamais	☐ Parfois	☐ Souvent	☐ Presque toujours
2.	Je me sens nerveux et agité	☐ Presque jamais	☐ Parfois	☐ Souvent	☐ Presque toujours
3.	Je suis content de moi	☐ Presque jamais	☐ Parfois	☐ Souvent	☐ Presque toujours
4.	Je voudrais être aussi heureux que les autres semblent l'être	☐ Presque jamais	☐ Parfois	☐ Souvent	☐ Presque toujours
5.	Je me sens un raté	☐ Presque jamais	☐ Parfois	☐ Souvent	☐ Presque toujours
6.	Je me sens paisible	☐ Presque jamais	☐ Parfois	☐ Souvent	☐ Presque toujours
7.	Je suis calme, détendu et de sang froid	☐ Presque jamais	☐ Parfois	☐ Souvent	☐ Presque toujours
8.	J'ai l'impression que les difficultés se multiplient à un point tel que je ne peux les surmonter	☐ Presque jamais	☐ Parfois	☐ Souvent	☐ Presque toujours
9.	Je m'inquiète trop à propos de choses qui n'en valent pas la peine	☐ Presque jamais	☐ Parfois	☐ Souvent	☐ Presque toujours

10.	Je suis heureux	☐ Presque jamais	☐ Parfois	☐ Souvent	☐ Presque toujours
11.	J'ai des pensées qui me tourmentent	☐ Presque jamais	☐ Parfois	☐ Souvent	☐ Presque toujours
12.	Je manque de confiance en moi	☐ Presque jamais	☐ Parfois	☐ Souvent	☐ Presque toujours
13.	je suis sûr de moi	☐ Presque jamais	☐ Parfois	☐ Souvent	☐ Presque toujours
14.	Je prends facilement des décisions	☐ Presque jamais	☐ Parfois	☐ Souvent	☐ Presque toujours
15.	Je ne me sens pas à la hauteur	☐ Presque jamais	☐ Parfois	☐ Souvent	☐ Presque toujours
16.	Je suis content	☐ Presque jamais	☐ Parfois	☐ Souvent	☐ Presque toujours
17.	Des pensées sans importance me trottent dans la tête et me tracassent	☐ Presque jamais	☐ Parfois	☐ Souvent	☐ Presque toujours
18.	Je ressens les contretemps si fortement que je ne peux les chasser de mon esprit	☐ Presque jamais	☐ Parfois	☐ Souvent	☐ Presque toujours
19.	Je suis quelqu'un de calme	☐ Presque jamais	☐ Parfois	☐ Souvent	☐ Presque toujours
20.	Je suis tendu ou agité dès que je réfléchis à mes soucis et problèmes actuels	☐ Presque jamais	☐ Parfois	☐ Souvent	☐ Presque toujours

Echelle d'Anxiété-Etat de Spielberger

Questionnaire d'anxiété Etat de Spielberger

Date de réalisation: I__I__I/I__I__I/I__I__I__I__I

<u>Instruction</u> :

Ci-après figurent un certain nombre de déclaration que les gens utilisent souvent pour se décrire. Lisez chacun des énoncés et cochez dans le case appropriée de droite ce qui convient le mieux à la façon dont vous vous sentez maintenant avant cette compétition ; Il n'existe ni bonnes ni mauvaises réponses. Ne passez pas trop de temps sur chacun des points, mais donnez la réponse qui semble décrire le mieux ce que vous ressentez dans cette situation. Répondez à toutes les questions et ne cochez qu'une case pour chacune d'entre elles.

A présent, répondez à la liste suivante par : Pas du tout, un peu, modérément, beaucoup

1.	Je me sens calmer	☐ Pas du tout	☐ Un peu	☐ Modérément	☐ Beaucoup
2.	Je me sens sûr de moi	☐ Pas du tout	☐ Un peu	☐ Modérément	☐ Beaucoup
3.	Je suis tendu	☐ Pas du tout	☐ Un peu	☐ Modérément	☐ Beaucoup
4.	Je me sens contraint	☐ Pas du tout	☐ Un peu	☐ Modérément	☐ Beaucoup
5.	Je me sens à mon aise	☐ Pas du tout	☐ Un peu	☐ Modérément	☐ Beaucoup
6.	Je me sens bouleversé	☐ Pas du tout	☐ Un peu	☐ Modérément	☐ Beaucoup
7.	Je m'inquiète à l'idée de malheurs possibles	☐ Pas du tout	☐ Un peu	☐ Modérément	☐ Beaucoup
8.	Je me sens satisfait	☐ Pas du tout	☐ Un peu	☐ Modérément	☐ Beaucoup
9.	J'ai peur	☐ Pas du tout	☐ Un peu	☐ Modérément	☐ Beaucoup
10.	Je me sens bien	☐ Pas du tout	☐ Un peu	☐ Modérément	☐ Beaucoup
11.	J'ai confiance en moi	☐ Pas du tout	☐ Un peu	☐ Modérément	☐ Beaucoup
12.	Je me sens nerveux	☐ Pas du tout	☐ Un peu	☐ Modérément	☐ Beaucoup
13.	Je suis agité	☐ Pas du tout	☐ Un peu	☐ Modérément	☐ Beaucoup

14.	Je me sens indécis	☐ Pas du tout	☐ Un peu	☐ Modérément	☐ Beaucoup
15.	Je suis détendu	☐ Pas du tout	☐ Un peu	☐ Modérément	☐ Beaucoup
16.	Je suis content	☐ Pas du tout	☐ Un peu	☐ Modérément	☐ Beaucoup
17.	Je suis inquiet	☐ Pas du tout	☐ Un peu	☐ Modérément	☐ Beaucoup
18.	Je me sens troublé	☐ Pas du tout	☐ Un peu	☐ Modérément	☐ Beaucoup
19.	Je me sens stable	☐ Pas du tout	☐ Un peu	☐ Modérément	☐ Beaucoup
20.	Je me sens dans de bonnes dispositions	☐ Pas du tout	☐ Un peu	☐ Modérément	☐ Beaucoup