HYPSEM Protocol
Version 1.1 of 02/11/2021

INFORMATION NOTE

TITLE OF THE STUDY :

Multicenter interventional study comparing the consumption of analgesics during a Shoulder dislocation reduction maneuver, in the emergency department, with and without the use of hypnosis (HYPSEM)

INFORMATION FOR THE PATIENT

Madam, Sir,

You have an anterior shoulder dislocation.

The promoter CHR Metz Thionville (1 allée du Château, CS 45001, 57085 Metz Cedex 03) and the investigating physician :

Title, Name, First name
Department name
Name of the establishment
Address
Phone number

offer you the opportunity to participate in research involving humans with minimal risks and constraints.

The purpose of this document is to provide you with information about the study for which you are being asked. Please read it carefully and ask any questions you may have of the investigator or his or her designate if you need more information. This document has been written to explain the research procedure to you. You have a period of reflection, if necessary.

Your participation in this study is entirely voluntary. You can leave this study at any time without any consequences for your care or for your relationship with the investigating physician. You can also leave the study if your doctor thinks it is best for you.

The effectiveness of hypnosis in pain management has already been demonstrated in several medical specialties such as obstetrics and surgery. However, there is very little data on the influence of hypnosis in emergency medicine and particularly in acute trauma.

Hypnosis uses natural involuntary skills to improve stress and pain management. The hypothesis of this research is that a hypnosis session during a shoulder dislocation reduction maneuver could have an impact on pain medication consumption.

PURPOSE OF THE STUDY

The main objective of the HYPSEM study is to compare the consumption of analgesics during a shoulder dislocation reduction maneuver with and without the use of hypnosis.

Secondary objectives included pain study, whether or not sedatives were used, your and the practitioner's satisfaction with the maneuver, number of reduction attempts, and time in the emergency room.

CONDUCT OF THE STUDY

This study is multicentric, in total 7 centers are involved:

- CH of Fleyriat
- CHR Metz-Thionville
- Sarreguemines Hospital
- CH Saint Joseph Saint Luc
- Lyon South University Hospital
- CH Vienna
- North-Western CH of Villefranche

In this study, the medical management is not modified. Only the addition of a hypnosis session during your care differs from current practice. This addition will be determined by a random draw.

Inclusion in this research will only be possible if a hypnosis trained caregiver is available. The draw will be done after your oral consent has been obtained to determine which group you will be assigned to. This study has two groups: the hypnosis group and the control group.

For the hypnosis group

During the hypnosis session, you will be asked to choose a pleasant life experience that will be relived throughout the procedure. If analgesia sedation is insufficient under hypnosis, the physician will add analgesia and/or sedation medication in accordance with standard care procedures.

Once the appropriate level of trance is reached, the reduction maneuver is started by the doctor. The hypnosis session will end at the end of your treatment to reduce your shoulder dislocation.

For the control group

The physician will institute sedation analgesia in accordance with the usual protocols of the service.

The administration of analgesics will be done according to your feelings in order to relieve your pain.

In both groups, the maneuver is performed according to the usual management. Your arm will be immobilized at the end of the maneuver and continuous monitoring will be performed if you have received medication that requires it.

This study will involve 44 patients, recruited over a projected period of 5 months in the various centers involved.

PARTICIPATION **TIME**

Your participation in the study lasts only as long as it takes to reduce your shoulder dislocation in the emergency room.

DATA COLLECTED

During the course of the study, the investigating physician will note:

- Your age
- The group you were assigned to (control or hypnosis group)
- Your usual treatments and will evaluate the drug consumption during the maneuver
- Your pain before, during and after the procedure. Your pain will be evaluated using a numerical scale ranging from 0 to 10. Knowing that 0 corresponds to no pain and 10 to maximum pain.
- The time you spend in the emergency room
- Your hemodynamic parameters before, during and after the maneuver (blood pressure, heart rate, oxygen saturation, respiratory rate)
- Your overall satisfaction during care (on a scale of 1 to 5 with 1=excellent and 5=catastrophic)
- What, if any, adverse events have occurred

MEDICAL EXPENSES

Your collaboration in this biomedical research protocol will not involve any financial participation on your part.

EXPECTED BENEFIT(S)

This study could improve the management of pain in the emergency room, reduce the adverse effects of analgesics, and reduce the time spent in the emergency room by decreasing the time spent on post-reduction monitoring. Depending on the outcome of the randomization, you will either receive the current

recommended management or a hypnosis session in addition to the current management. In the latter case, the individual benefits cannot be guaranteed by the investigating physician. Indeed, this study seeks to prove the effectiveness of hypnosis during a reduction of shoulder dislocation in reducing the consumption of analgesics.

POTENTIAL RISKS

There are few adverse effects described following a simple hypnosis session, especially in the context of hypnoanalgesia (hypnosis to relieve pain). In the literature, a persistence of a residual hypnotic state at the end of the treatment, an abreaction (emotional discharge accompanying the appearance in the field of consciousness of an affect previously repressed because of its painful character), anxiety and a decompensation of psychotic disorders are described. In practice, if the contraindications to the use of hypnosis are respected and the session is carried out by a properly trained hypnotherapist, these undesirable effects are very rarely observed. If you experience any of the side effects described above, inform the doctor who is treating you immediately.

CONTRAINTS

To participate in this clinical study, you must be covered by a social security plan and you will not be able to participate in any other research at the same time. However, once you have completed your treatment to reduce your shoulder dislocation, you are free to participate in other clinical studies. Pregnant women cannot be included in this study either.

MY RIGHTS

The collection and use of data is based on your oral consent, which will be obtained at the time of your inclusion in the study, after clear and fair information. You have the right to refuse to participate in the study without justification, prejudice, liability or impact on your care. Similarly, you have the right to withdraw your consent at any time, without justification, by contacting the study physician. This decision will not affect the quality of your care. Once you withdraw your consent, you will no longer be able to participate in the study and no new data will be collected as part of this research. However, the data already collected will continue to be used and processed in order to maintain the integrity of the study in accordance with the applicable data protection law.

The processing of data is subject to Law No. 78-17 of January 6, 1978 on data processing, files and freedoms as amended and the European Regulation (EU) 2016/679 of April 27, 2016 on the protection of personal data (RGPD).

In accordance with Article 6 of the GDPR, this processing is necessary for the performance of a public interest task.

In the context of this research, your personal data will be processed in order to analyze the results of the research in relation to its objectives. This data will be

identified by a code number including an inclusion number (corresponding to the chronological order of their inclusion and the center number) as well as the 1ère letter of the last name and the 1ère letter of the first name. If necessary, they may also be transmitted to the authorized health authorities. In all cases, they will be used under conditions that guarantee their confidentiality and only the data necessary for the research will be collected. All data and information concerning you will remain strictly confidential.

This data processing is part of the MR001 reference methodology for which the CHR
Metz-Thionville, as sponsor of the study, signed a compliance undertaking on May 11, 2009 (n°1363172). In accordance with this reference methodology, the processing of personal data of persons undergoing research must be for the sole purpose of carrying out research of public interest.

It will be accessible only to the persons participating in this research and to the persons entrusted by the sponsor with the quality control of the study.

The person responsible for processing the data in the context of this study is the CHR Metz-Thionville, promoter of the study.

However, you have the right to object to your data being processed automatically. If you agree, you have a right of access to the information concerning you in order to verify its accuracy and, if necessary, to rectify, complete or update it, a right to object to its use, and a right to erase this data. In addition, you have a right to portability of your personal data (Article 20 of the GDPR), which allows you to receive the data, in a structured format, and to transmit it to another data controller. It is important to note that data portability does not automatically trigger data erasure.
However, portability cannot be used as a means to postpone or refuse erasure.
If you have any questions about data protection or if you have any difficulties in exercising your rights, you can contact the data protection officer at dpo@chr-metzthionville.fr or the investigating physician in charge of you.
You can also access all your medical data directly, or through the investigating physician, in accordance with the provisions of article L1111-7 of the Public Health Code. You will find the contact details of your investigator on the first page of this document.

In accordance with the General Data Protection Regulation (GDPR 2016/679 of the European Parliament and of the Council of 27 April 2016), health data will be processed for the purpose of scientific research in compliance with the fundamental rights and interests of the person undergoing the research (Article 9, paragraph i and j). If you believe that the study data, concerning you are used in violation of applicable data protection laws, you have the right to make a complaint to the supervisory authority responsible for

compliance with data protection laws in France: Commission Nationale de l'Informatique et des Libertés-CNIL, 3 place de Fontenoy-TSA 80715- 75334 PARIS cedex 07.

No transfer of your data outside the European Union is planned in the context of this research.

The study data will be kept by the sponsor and the investigating centers until the final research report is written. At the end of the research, the data will be archived for 15 years in accordance with the archiving rules for clinical studies.

This study is subject to the regulations governing research involving the human person in accordance with Title II of Book 1er of the Public Health Code and its implementing regulations. This is a category 2 research (interventional research with minimal risks and constraints). In accordance with articles L. 1121-1 and following of the Public Health Code, the Comité de Protection des Personnes Sud-Est IV studied this research project and issued a favorable opinion for its implementation on 03/11/2021. Moreover, the French National Agency for the Safety of Medicines and Health Products (ANSM) was informed on 19/11/2021 of the implementation of this study.

In accordance with the regulations in force, an insurance policy has been taken out by the Promoter with SHAM (18 rue Edouard Rochet 69372 LYON cedex 08) contract number: 134516/04. This civil liability insurance covers damage that may result from the research.

A description of this study will be available at http://www.ClinicalTrial.gov. This site will not contain any personally identifiable information. Similarly, the publication of the results of the study will not include any individual results. In accordance with article L 1122-1 of the French Public Health Code (law of March 2002 on patients' rights), the overall results of the study may be communicated to you if you wish.

If you have any questions during your participation in this study, you may contact the study investigator.

Thank you for taking the time to read this newsletter.

TO BE COMPLETED BY THE INVESTIGATOR
I, the undersigned Doctor ..... (NAME in capital letters) confirm that I have fully explained to ..... (Name and first name of the patient in capital letters) the purpose and the modalities of this study as well as its potential risks and that I have obtained his oral consent.

Date:	Signature: