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Study protocol: hypnosis versus standard care for shoulder dislocation reduction in the emergency department – a multicentre, randomised, controlled study protocol

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ABSTRACT

Introduction Anterior shoulder dislocation is a common reason for consultation at the emergency department (ED). Hypnosis could be a safe and effective alternative therapy for pain relief during shoulder dislocation reduction but nowadays, evidence is not sufficient. The main objective of this study is to show that reduction under hypnosis is associated with a decrease in the use of analgesic compared with usual care.

Methods and analysis We will conduct an interventional, controlled, multicentre, randomised study. A total of 44 patients with shoulder dislocation will be randomised in two groups: the hypnosis group (N=22) and the usual care group (N=22). The primary endpoint will be the comparison of morphine equivalent analgesic consumption during a shoulder dislocation reduction manoeuvre. Secondary endpoints will include haemodynamic parameters monitoring, patient and practitioner satisfaction using a Likert scale, use of coanalgesic or sedative drugs, number of reduction attempts and time spent at ED. Adverse events will be recorded. Statistical analysis will include parametric tests, multivariate linear regression and descriptive statistics.

Ethics and dissemination This study has received ethics approval from the Comité de Protection des Personnes of Sud-Est IV on 03/11/2021 (ANSM informed on 19 November 2021). The results will be published in scientific articles and communicated in national and international conferences.

Trial registration number ClinicalTrial.gov: NCT04992598; National Clinical trial no ID RCB : 2021-A01382-39

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ To our knowledge, this is the first multicentric prospective and randomised study to evaluate the effectiveness of hypnosis in the emergency department.
⇒ The method is rigorous and well detailed. The protocol is written by a multidisciplinary team.
⇒ This study is suitable for clinical practice.
⇒ Blinding is not suitable because of the characteristics of hypnosis and the fact that the session must be performed during the reduction.
⇒ A possible bias may be due to different levels of experience between the people that will perform hypnosis but a standardisation session is offered.

BACKGROUND

Anterior shoulder dislocation, also known as anterior glenohumeral dislocation, is a common reason for the consultation at the emergency department (ED), with an estimated annual incidence of 17–24 per 100 000 patients. That represents 45% of all dislocations.[1 2] Most of the time, this is reduced in ED. This is diagnosed thanks to a questioning, a clinical and radiological examination.

Any dislocated shoulder must be reduced quickly to avoid reflex contraction of the muscles and to relieve the patient as fast as possible. Indeed, this is a very painful disease for which there is no specific recommendation for both the reduction manoeuvre and the sedation and analgesia procedure we must use.[3] The result is a development of disparate practices. Concerning the reduction technique, there are more than 50 different techniques but none is validated as a gold standard despite several comparative studies.[4 5] Different levels of analgesia or sedation may be required, depending on the type of dislocation, the associated lesions including fractures and nerve compression, the reduction technique, the operator and the patient (history, pain intensity). The necessary means

for the successful reduction of a limb dislocation are most often part of a procedural sedation-analgesia (PSA).[6] PSA consists in analgesia and moderate to deep brief sedation used during painful procedures.[7] Many molecules are available for PSA such as midazolam, propofol, fentanyl, ketamine or etomidate.[8] Several studies have been conducted to assess a reference among these molecules in the shoulder dislocation reduction but none has been able to prove superiority. PSA requires continuous and close monitoring of the patient, as the molecules used can lead to haemodynamic, respiratory or neurological adverse events.[9] Hypnosis could be a safe alternative to drugs. The American Psychological Association defines the hypnotic state as 'a state of consciousness involving focused attention and decreased sensitivity to the environment, characterised by an increased capacity to respond to suggestion'.[10] The term hypnosis is used to define the hypnotic process that induces this state. More and more neuroscience studies try to understand the mechanisms of hypnosis.[11–13] This modified state of consciousness is safe for the patient because it is above all a physiological state. The effectiveness of hypnosis in pain management was assessed in several medical specialties such as obstetrics, surgery, dentistry.[14–18] Several meta-analyses assessed that medical hypnosis is a safe and effective complementary technique for pain management. In the ED, there is only a few low-level evidence for the use of hypnosis.[19 20] In addition, pain is still insufficiently managed in the ED, especially in case of acute trauma.[21 22] Hypnosis could have a real interest for pain treatment in the ED, alone or in association with other medications. Our primary hypothesis is that a hypnosis session during a shoulder dislocation reduction manoeuvre could reduce the frequency of the consumption of three or more morphine equivalent for 25%–5% of the patients. Our secondary hypothesis is that it would improve haemodynamic parameters (difference of 2%), patient and practitioner satisfaction (Likert scale with 1 point difference), decrease the number of reduction attempts,[1] and decrease the amount of sedation used and time spent in the ED.

METHODS

Aims, design and study setting

Primary objective

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

Study settings

This study is conducted in seven French ED which are: the Fleyriat Hospital in Bourg-en-Bresse, the Metz-Thionville Regional Hospital (CHR Metz-Thionville), the Sarreguemines Hospital, the Saint Joseph Saint Luc Hospital in Lyon, the South Lyon University Hospital, the Vienne Hospital and the North-Western Hospital in Villefranche.

Patient and public involvement

No patient involved.

Study design

This study is an interventional, randomised, multicentre, usual care study. It will run from February 2022 to July 2022. Patient prescreening is done by the Intake Nurse Organiser (IOA). The patient is given a brief, clear and fair oral information about the study and the caregiver collects his oral consent. If the patient's condition permits it, the patient receives written information at the same time as the oral information (information not available in online supplemental appendix). If not, the investigator gives the information note to the patient after the reduction procedure. Inclusion in this research is only possible if a hypnosis qualified caregiver (nurse or physician, no specific level required) is available at the time of inclusion. The collection of oral consent is recorded in the medical file by the investigating physician. Randomisation is carried out by opening numbered envelopes provided by the coordinating centre. The study design is summarised in figure 1.

Inclusion criteria

Patients going to an ED involved in the study who meet all of the following criteria will be included :

- Patient 18 years and over.
- Checked in the ED for an anterior shoulder dislocation, confirmed thanks to X-ray.
- Have given oral consent to participate in the study.
- Is affiliated or is a recipient of a social security plan.
- An hypnosis qualified staff member (nurse, nurse's aide or physician) is available at the patient admission time.

Non-inclusion criteria

The criteria for non-inclusion are:

- Patients with a shoulder fracture on X-ray.
- Patients with a shoulder prosthesis.
- Patients with recurrent dislocations.
- Patients who does not speak or understand the French language.
- Patients with cognitive dysfunction.
- Patients with a psychiatric history of psychosis.
- Patients who are deaf or hard of hearing.
- Patients under legal protection (guardianship, curatorship).
- Pregnant women.
- Patients who already had a prehospital reduction.

Randomisation

The randomisation list is established by the methodology of the Plateforme d'Appui à la Recherche Clinique (PARC) of the CHR Metz Thionville before the beginning of the research. It will be kept in a protected computer file at the PARC of CHR Metz-Thionville. The two groups' numbers (hypnosis or control) are balanced with a ratio of 1:1. The sealed randomisation envelopes will be available for the emergency physicians and under the responsibility of the

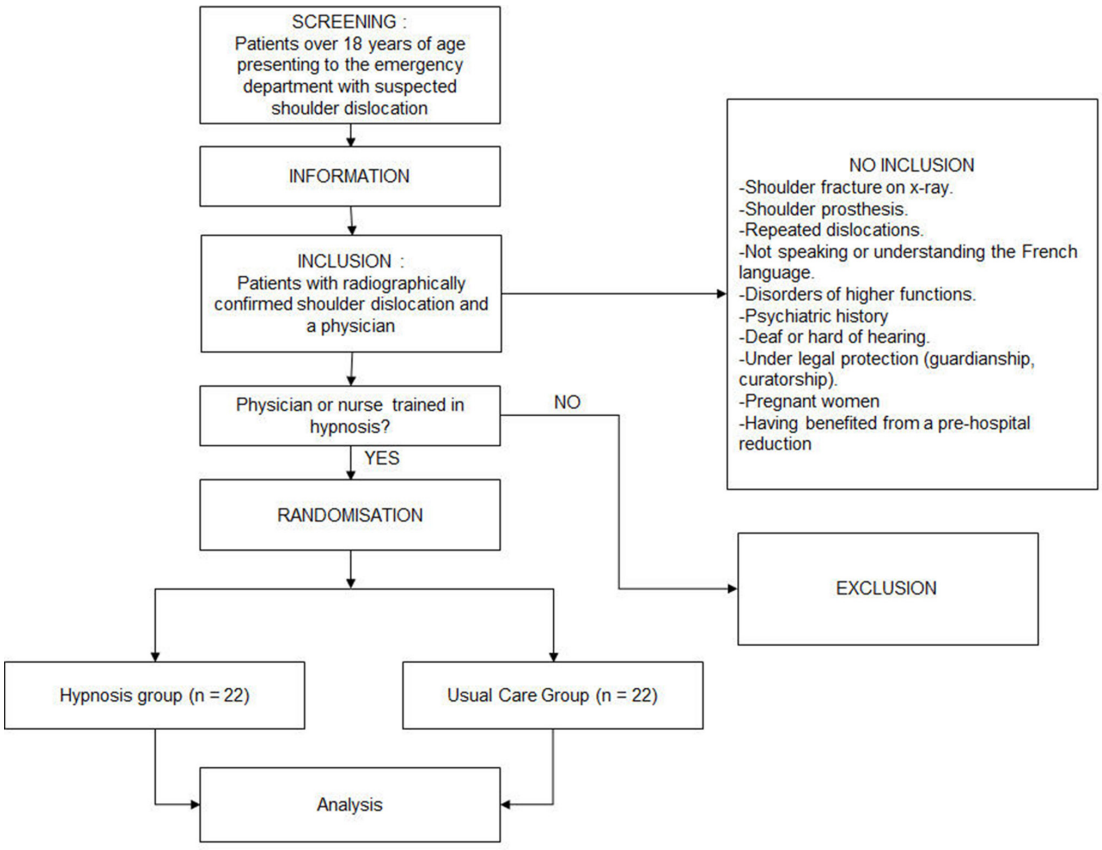

Figure 1 Flow chart of study.

main investigator of each centre. Randomisation will be performed in the ED, on arrival of an eligible patient, if a qualified caregiver is available, by chronological drawing of numbered sealed envelopes after oral consent of the patient. Blinding is not applicable for this study because there is no 'placebo hypnosis'.

Hypnosis intervention

The hypnosis intervention is delivered by a doctor or a nurse qualified. Given the limited number of caregivers trained to perform hypnosis in the ED and in order to maximise the number of patients included in the hypnosis group, there will not be any level of training or year of practice required. To overcome this bias, a preliminary training session will be conducted by videoconference to formalise and align the practices during the implementation of the study. In addition, an outline session will be provided and the hypnotherapist will be allowed to adapt it during the session according to the patient's needs. The hypnosis session is standardised and includes suggestions for analgesia and muscle relaxation. The hypnotic state is described to the patient as 'a state of mental focus on a pleasant life experience that provides a distraction during the manoeuvre'. The word 'hypnosis' will be used intentionally in the hypnosis arm to potentiate the effect of this therapy. In the hypnosis with the usual care group (HYP group), the patient is asked to choose a very pleasant life experience to be relieved during the manoeuvre. An hypnotic state is then induced. The hypnosis session will precede any drug therapy. If analgesia sedation is not sufficient under hypnosis, the physician will add analgesic and/or sedative medications as well as in the usual care group. Once patients are considered to be at an adequate level of trance (±10 min), the reduction manoeuvre is initiated by the physician while continuing the hypnosis session. Termination will end the hypnosis session and bring the patient out of the trance state.

Standard care

In the usual care group, each physician will perform the reduction as they usually do.

Procedure

In both groups, the patient will be monitored continuously (blood pressure (BP), heart rate (HR), respiratory rate (RR) and saturation) for a shoulder dislocation reduction manoeuvre. Pain management will be performed according to the pain assessment with the objective of EN<4, according to current recommendations. In the hypnosis group, hypnosis will be the first treatment introduced; it can be completed by the analgesics and/or sedatives medications afterwards if needed. In both groups, the type of shoulder dislocation reduction manoeuvre will be reported.

At the end of the manoeuvre, the patient's arm is immobilised elbow to body in both groups. The success of the manoeuvre will be checked by a clinical and radiographic examination. The instructions for further management

are given to the patient without modification of the practices. Continuous, monitored surveillance will continue after the procedure if the patient received drugs that require it.

Primary outcome measure

The amount of analgesics administered from the moment the patient arrives in the ED until the end of the reduction manoeuvre will be collected in milligrams by the nurse in charge of the patient as the injections will be necessary. The names of the drugs used will be recorded on the case report form (CRF). In order to compare the dose of morphine with each other, we will convert them into equipotent doses.[23] We consider that 2 mg of morphine for patients who weigh less than 60 kg or 3 mg of morphine for patients who weigh more than 60 kg corresponds to one dose. Patients will be classified into three groups: patients who required one dose or less; those who required two doses and those who required more than three doses.

Secondary outcome measure

The patient's pain will be assessed by self-report using a numerical scale pain graduate from 0 to 10 cm (0 cm=no pain; 10 cm=worst pain) before the procedure, every 3 min during the procedure (the worst numeric pain scale will be retained) and 5 min after the end of the procedure. In addition, the nurse will perform a hetero-evaluation pain scale during the procedure (numeric pain scale 0=no pain; numeric pain scale 10=worst pain). We expect an improvement of three points.[13]

HR, BP, oxygen saturation (Sat) and RR will be recorded every 3 min from the time the patient enters the continuous monitoring room until discharge. We expect a global difference of 2.5%.[18]

The use of sedatives, the name of the drugs and the amount used during the manoeuvre will be reported by the nurse on the CRF. We expect a 25% reduction in overall sedative use, based on clinical relevance.

The number of reduction attempts will be recorded in the CRF. If the physician needs more than two reduction attempts, the patient will be managed according to the recommendations for the management of shoulder dislocation (surgical opinion).

Once the manoeuvre is completed, the physician in charge of the patient will take care to report in the CRF his comfort during the procedure using a self-assessment and the patient's satisfaction using a Likert scale of five items. We expect a difference of 1 point on the Likert scale for the hypnosis group.

The time spent in the ED will be collected in the CRF in minutes afterwards, once the patient will leave the department. We expect a difference of 1 hour between the two groups.

Confounding factors

We identified several confounding factors that will be collected in CRF, such as:

- Patient characteristics.
- Sedatives used.
- Type of manoeuvre (Milch, Kocher, Matsen, Hippocrate, Chair method or other).
- Patient under beta-blocker or antihypertensive treatments (interaction on haemodynamic parameters).
- Experience of the caregiver providing the hypnosis session (declarative).

Safety evaluation

Possible adverse events related to the study or to the management will be investigated from the beginning of the drug administration until the patient's discharge. They will be reported in the CRF. These events may be the persistence of a residual hypnotic state at the end of the treatment, abreaction (emotional discharge where an effect previously repressed because of its painful nature occurs in the field of consciousness of the patient) (59,60), nausea and vomiting, haemodynamic adverse effects, respiratory adverse effects, neurological adverse effects, allergic reaction, anaphylaxis.

Quality control

Data process will be carried out under the responsibility of the PARC of the CHR Metz-Thionville. The data will be entered and proofread in a Cleanweb data entry mask. The data validation and freezing processes will be carried out according to the current procedures at the PARC of the CHR Metz-Thionville.

Sample size calculation

We expect that 25% of the patients will need three or more equipotent doses of analgesics in the control group, and 5% in the hypnosis group.[23] Under these conditions and with an alpha risk set at 5%, it is necessary to include 35 patients per group, or 70 patients in total, to achieve a power of 80%.

Statistical analysis

The comparability of the groups will be assessed using Fisher's exact tests (qualitative factors) or Student's t-tests (quantitative factors). The frequency of three or more equipotent analgesic doses consumption will be compared between the two groups (hypnosis and no hypnosis) using a Fisher's exact test and then multivariate logistic regression to account for possible confounding factors. Qualitative secondary endpoints will be compared between groups using the same strategy, quantitative endpoints will be compared using Wilcoxon tests and then multivariate linear regressions. The analyses will be performed on an intention-to-treat basis. The significance level will be set at 5%.

ETHICS AND DISSEMINATION

The sponsor and the investigators undertake that this research will be carried out in compliance with the Public Health Code, as well as in accordance with Good Clinical Practice (I.C.H. version 4 of 1 May 1996 and decision of

24 November 2006) and the Declaration of Helsinki. This research has received an ID-RCB number 2021-A01382-39 on the ANSM website. This research has received a favourable opinion from the People Protection Committee of Sud-Est IV on 03/11/2021 (ANSM informed on 19/11/2021). This research is registered on ClinicalTrials.gov under the no NCT04992598. An opinion from the ethics committee has not yet been requested. The results will be published in scientific articles and communicated in national and international conferences.

DISCUSSION

To our knowledge, this is the first clinical multicentric and randomised study with a high level of evidence focused on hypnosis in the ED. This study relies on a prior training of the different caregivers to homogenise the practices. Hypnosis is clearly defined, as recommended in the literature, and a session outline is proposed, although the hypnotherapist is free to modify the session as needed according to the patient's reaction.[24] The script includes direct suggestions for analgesia as the literature shows that hypnotic interventions are most effective when they do that.[25] In a meta-analysis, Patterso*n et al* show that several studies succinctly describe their experimental intervention, but only Lang *et al* describe a carefully detailed procedure.[18 26]

Although hypnosis had shown to be effective in the management of chronic and acute pain, the various studies about hypnosis had lacked a high level of evidence.[24 26 27] In order to provide reliable evidence of the effects of hypnosis during a shoulder reduction procedure, we carefully designed this study and included full details of the implementation plan. Randomisation generated by chronological envelope drawing will be adopted to minimise selection bias, and blocked randomisation will be applied to ensure prognostic balance between groups. Our primary endpoint is robust and objective, based on drug quantity. We purposely did not use pain assessment by scales as the primary endpoint; these scales, although validated, are complex to use in clinical research and could induce bias depending on how the request is formulated and on the expected answer. However, it seems interesting to have these pain scales as a secondary criterion, so that we have complementary pain index : one of the patient's perception, one of physician behaviour and a biological one.

If hypnosis leads to reduced consumption of analgesic during a shoulder dislocation reduction procedure, the use of hypnosis would be recognised and considered as a reasonable complementary and alternative therapy in patients with shoulder dislocation. If our results are consistent with the literature, our study should show a significant difference in the amount of analgesics used during a shoulder dislocation reduction procedure.[28 29] Under strict quality control, we expect the results of this study to provide high-quality evidence to determine whether hypnosis would reduce the amount of pain medication used during a shoulder dislocation reduction manoeuvre in the ED. More broadly, our study could improve ED pain management with hypnosis, decrease analgesic-related adverse effects, and reduce ED time by reducing postreduction monitoring time. In addition, our study could change the different beliefs around hypnosis from the hospital community and lead more emergency physicians to train in hypnosis to improve their practice. It will then be interesting to extend our study to other painful procedures performed in the ED, or even in the prehospital setting.

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Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Consent obtained directly from patient(s).

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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: