**Protocol prospective interventional trial**

**Full title**:

**Protocol acronym/short title**:

**Version and date of final protocol:**

**Sponsor**:

**Principal Investigator**:

**Sub-investigator**:

Signatures

Principal Investigator Date

Frederic De Schrijver

Subinvestigator Date

Hannah De Houwer

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**1. Study Synopsis**

Title of clinical trial

Protocol Short Title/Acronym

Sponsor name

Principal Investigator

Medical condition or disease under

investigation

Purpose of clinical trial

Primary objective

Secondary objective (s)

Trial Design

Endpoints

Sample Size

Summary of eligibility criteria

Maximum duration of treatment of a

Subject

Version and date of final protocol

Version and date of protocol amendments

**2. Background and rationale**

**3. Trial objectives and Design**

**3.1 Trial objectives**

**3.2 Primary endpoints**

**3.3 Secondary endpoints**

**3.4 Trial Design**

**3.5 Study diagram**

**Eligibility**:

**Inclusion:**

**Radiology:**

**Anamnestic:**

**Clinic:**

**Excluded:**

**Randomisation**

**Group 1:**

**Group 2:**

**2 weeks postoperative:**

**6 weeks postoperative:**

**Anamnestic:**

**Clinic:**

**3 months postoperative:**

**Anamnestic:**

**Clinic:**

**1 year postoperative:**

**Anamnestic:**

**Clinic:**

**Analysis**

**3.6 Trial Flowchart**

**4. Selection and withdrawal of subjects**

**4.1 Recruitment of subjects**

**4.2 Inclusion criteria**

**4.3 Exclusion criteria**

**4.3 Expected duration of trial**

**5. Trial Procedures**

**5.1 By visit**

* + *First screen visit*
  + *Surgical intervention*
  + *Two weeks postoperative*
  + *Six weeks postoperative*
  + *Three months postoperative*
  + *One year postoperative*

**5.2 Laboratory tests**

**5.3 Other investigations**

**6. Assessment of efficacy**

Assessment of efficacy does not apply in this study, since both surgical treatment options are well described standard of care procedures.

**7. Assessment of Safety**

**7.1 Specification, timing and recording of safety parameters**

**7.2 Procedures for recording and reporting adverse events (AE)**

**8. Compliance and withdrawal of subjects**

**a. Subject compliance**

Since no medication will be administered, and our intervention comprises a one event surgical technique, compliance will not be recorded concerning the intervention.

**b. Withdrawal of subjects**

Subjects will be able to withdraw their consent from this trail at any given time. Withdrawal will be recorded on paper, follow-up visits will continue according to standard of care.

**9. Randomisation**

**10. Blinding**

**11. Statistics**

**11.1 Sample size**

**11.2 Analysis**

**12. Quality assurance**

Quality assurance will be maintained by providing well described procedure leaflets for both surgical treatment techniques, postoperative care and physical therapy regimes, pre- and postoperative outcome measurements and completion of questionnaires. These leaflets are provided in Dutch.

**13. Direct access to source data and documents**

Direct access to source data and other patient related documents will be provided in case of EC

review or internal trial-related monitoring, as no external partner to this study is involved.

**14. Ethics and regulatory approvals**

The trial will be conducted in compliance with the principles of the Declaration of Helsinki (current version), the principles of GCP and in accordance with all applicable regulatory requirements. This protocol and related documents will be submitted for review to the Ethics Committee xx for advice.

The study can and will be conducted only on the basis of prior informed consent by the subjects, or their legal representatives, to participate in the study. The research site shall obtain a signed informed consent form (ICF) for all patients prior to their enrollment and participation in the study in compliance with all applicable laws, regulations and the approval of the (local) Ethics Committee, if required. The research site shall retain such ICFs in accordance with the requirements of all applicable regulatory agencies and laws.

The investigator and the research site shall treat all information and data relating to the study disclosed to research site and/or investigator in this study as confidential and shall not disclose such information to any third parties or use such information for any purpose other than the performance

of the study. The collection, processing and disclosure of personal data, such as patient health and medical information is subject to compliance with applicable personal data protection and the processing of personal data (Directive 95/46/EC and Belgian law of December 8, 1992 on the Protection of the Privacy in relation to the Processing of Personal Data).

Any subsequent protocol amendments will be submitted to the EC for approval.

If required, the local Ethics Committee will be provided with progress reports, and a copy of the Final

Study Report.

**15. Data Handling and Management**

**16. Translational research**

No biological material will be collected, shipped, stored or used in this study.

**17. Publication Policy**

Authorship to publications will be determined in accordance with the requirements published by the International Committee of Medical Journal Editors and in accordance with the requirements of the respective medical journal.

**18. Insurance/Indemnity**

**19. Financial Aspects**

**Appendix I: Outcome scores**

*Numeric Pain Rating Scale*

The numeric pain rating scale is an aspecific scale, comprising 11 numbers going from 0 to 10, in which 0 means no pain and 10 the maximum of predictable pain. The patient needs to circle the number that represents the gravity of his/her pain the most, over the course of the past week. We must note that because the patient can only account his/her pain a single number, the NPRS is less sensitive to minor changes than VAS scoring (Visual Analogue Scale).

*Quick Disability of Arm, Shoulder and Hand Questionnaire*

The QuickDASH is a shortened version of the DASH scoring system, a patient-based standardized questionnaire, which evaluates impairments and activity limitations, as well as participation restrictions for both leisure activities and work. It consists of 11 items to measure physical function and symptoms in people with any or multiple musculoskeletal disorders of the upper limb. Similar to the DASH, each item has five response options (1 = no difficulty; 2 = mild difficulty; 3 = moderate difficulty; 4 = severe difficulty; 5 = unable). From the item scores, a summative score is calculated. The final score ranges between 0 (no disability) and 100 (the greatest possible disability). Only one missing item can be tolerated, and, if two or more items are missing, the score cannot be calculated(34). DASH and QuickDASH scoring systems are validated in Dutch(35).

**20. References**