Endogenous Pain Modulation in Patients with Shoulder Arthroplasty for Osteoarthritis

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Ethical review	Approved WMO
Status	Recruitment started
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON53872

Source
ToetsingOnline

Brief title
EPM study

Condition

- Joint disorders

Synonym
degenerative joint disease, Osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Reinier Haga Orthopedisch Centrum
Source(s) of monetary or material Support: Reinier de Graaf,Reinier Haga Orthopedisch Centrum

Intervention

- No intervention

Keyword: Osteoarthritis, painmodulation, Shoulder Arthroplasty

Explanation

N.a.

Outcome measures

Primary outcome

The main study parameters are CPM and TS values at baseline and at 3 and 6
 months after surgery, as well as the absence/presence of allodynia at baseline
 and at 3 and 6 months after surgery.

Secondary outcome

Secondary outcomes are painscores, pain catastrophizing and coping strategies
 at baseline and at 3 and 6 months after surgery.

Study description

Background summary

Although most patients experience significant pain relief after total shoulder arthroplasty (TSA), pain persists for some patients even after surgery. The endogenous pain system may be involved in persisting postoperative pain in total knee arthroplasty (TKA) and total hip arthroplasty (THA) patients, but this has never been studies for TSA patients. Furthermore, psychological factors and coping strategies may also be of interest but have not yet been extensively studied in TSA patients.

Study objective

The primary objective is to explore whether central sensitization and/or abnormal CPM responses are present in (a subgroup of) patients who will receive shoulder arthroplasty for osteoarthritis, and whether shoulder arthroplasty produces change in these measures of the endogenous pain modulatory system. The secondary objective, in case patients with altered endogenous pain modulation are found, is to explore if change in pain over time, psychological factors and coping strategies differ between patients with and without altered

pain modulation.

Study design

An exploratory prospective observational cohort study.

Study burden and risks

The burden of participation will consist of completing questionnaires at baseline and every month for six months after surgery. In addition, subjects will undergo psychophysical testing at 3 moments, which can lead to redness or a burning sensation of the skin during the first 24 hours after testing. We do not expect any additional risks associated with participation. There is no direct benefit for the participants.

Contacts

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Trial sites

Trial sites in the Netherlands

Reinier Haga Orthopedisch Centrum
Target size: 25

Reinier de Graaf Gasthuis (uitvoeren metingen, geen inclusiepatiënten)
Target size: 0

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age >= 18 yrs
- Scheduled to undergo primary total shoulder arthroplasty (TSA) or reversed shoulder arthroplasty (RSA) for primary shoulder osteoarthritis or cuff tear arthropathy
- American Society of Anesthesiologists score 1, 2 or 3
- Able to provide written informed consent

Exclusion criteria

- Regular use of anti-depressants or anti-epileptics for any purpose, including SNRIs and gabapentinoids
- The presence of any chronic pain disorder other than osteoarthritis
- Osteoarthritis in joints other than the affected shoulder, for which arthroplasty is/will be planned in the near future
• Difficulty with or inability to perform psychophysical testing (eg. in case of cognitive or psychiatric disorders)
- Difficulty with or inability to communicate with the investigators (eg. difficulty with the Dutch language, cognitive/memory disorders)

Study design

Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Single

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment started
Start date (anticipated):	04-03-2024
Enrollment:	25
Duration:	6 months (per patient)
Type:	Actual

Medical products/devices used

Product type:	N.a.

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N.a.

Ethics review

Approved WMO

Date:	17-10-2022
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	27-03-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	07-04-2025
Application type:	Amendment
Review commission:	METC LDD

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT05861960
CCMO	NL81143.058.22
Research portal	NL-007484