Dagboekstudie bij schouderprothesen: de eerste acht weken na de operatie en belangrijke voorspellers voor korte- en lange termijn uitkomsten

Gepubliceerd: 17-11-2017 Laatst bijgewerkt: 08-12-2023

Primary Objective To describe how patients experience the first eight weeks after shoulder arthroplasty, regarding pain and pain medication, shoulder function and quality of life. To determine the direct effect of patients' expectations on...

Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	Bot en gewricht therapeutische verrichtingen
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25734

Bron
NTR

Verkorte titel
Dagboekstudie bij schouderprothesen

Aandoening

- Bot en gewricht therapeutische verrichtingen

Aandoening

Dairy, Shoulder arthroplasty, Expectations, Postoperative trajectory Dagboek, Schoudervervanging, Verwachtingen, Postoperatief beloop

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: Reinier de Graaf Groep, afdeling orthopedie
Overige ondersteuning: Reinier de Graaf Gasthuis, Delft

Onderzoeksproduct en/of interventie

- Medische hulpmiddelen

Toelichting

Uitkomstmaten

Primaire uitkomstmaten
Postoperatieve pijn gedurende de eerste 8 weken, na 6 maanden en na 1 jaar

Schouderfunctie gedurende de eerste 8 weken, na 6 maanden en na 1 jaar

Kwaliteit van leven gedurende de eerste 8 weken, na 6 maanden en na 1 jaar

Tevredenheid

Toelichting onderzoek

Achtergrond van het onderzoek

SUMMARY

Background: To improve outcomes after shoulder arthroplasty (SA) it is essential to know which factors influence the outcome of SA. In total knee arthroplasty (TKA) and total hip arthroplasty (THA) research, the focus on the influence of psychological factors such as expectations, catastrophizing and optimism, as well as central sensitization (CS) and central pain modulation (CPM), increased in the last years. The effect of these constructs on the short-term and long-term outcomes is not completely clear: evidence regarding the effect of expectations on outcomes is inconsistent, while there is some evidence that catastrophizing and optimism influence or predict outcomes after surgery in general, and for TKA and THA in particular. For SA, very few studies have been performed on these topics. Therefore, it remains unclear whether these psychological constructs have similar effects in SA patients. Furthermore, it is still uncertain if an association between expectations and outcomes provides unique information on the role of expectations independent from catastrophizing, optimism, CS or CPM, or if these constructs interact with expectations.

Objective: The primary objectives of this study are to describe how patients experience the

first eight weeks after shoulder arthroplasty with regard to pain, pain medication, shoulder function and quality of life, and to determine the direct effect of patients' expectations on postoperative pain, shoulder function, quality of life and satisfaction scores, controlled for catastrophizing and dispositional optimism. The secondary objective is to determine the direct effect of early postoperative pain on persistent postoperative pain at six months, while controlling for or taking into account modifying or mediating effects of factors that were found to have an effect on early postoperative pain itself.

Study design: A multicenter prospective observational cohort study.

Study population: Patients who are scheduled to undergo SA at the orthopedic department of participating hospitals or at the participating orthopedic clinics. Primary study parameters/outcome: The main endpoints are postoperative pain, shoulder function, quality of life and patient satisfaction

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Since this study is solely an observational study in which patients complete questionnaires and will not undergo additional assessment compared with usual care, the burden of participation consists only of filling in sets of questionnaires at baseline, six months postoperatively and twelve months postoperatively. In addition, a daily diary will be kept for the first eight weeks, which will take approximately three minutes per day. We do not expect any risks associated with participation. There is no direct benefit for the participants.

Doel van het onderzoek

Primary Objective To describe how patients experience the first eight weeks after shoulder arthroplasty, regarding pain and pain medication, shoulder function and quality of life. To determine the direct effect of patients' expectations on postoperative pain, shoulder function, quality of life and satisfaction scores, while controlling for or taking into account modifying or mediating effects of catastrophizing and dispositional optimism (and, for the outcome 'pain', Central Sensitization Inventory score as well). Secondary Objectives To determine the direct effect of early postoperative pain on persistent postoperative pain at six months, while controlling for or taking into account modifying or mediating effects of factors that were found to have an effect on early postoperative pain itself

Onderzoeksopzet

T0: Pre-operatively

T1: During the 8 weeks after surgery

T2: 6 months post-operatively

T3: 1 year post-operatively

Onderzoeksproduct en/of interventie

T0: 8 short questionnaires

T1: The dairy with quentions about pain, shoulder function, quality of life and sleep.

T2: 9 short questionnaires

T3: 9 short questionnaires

The questionnaires are about expectations, pain, shoulder function, quality of life and complaints

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Leeftijd
Volwassenen (18-64 jaar)
Volwassenen (18-64 jaar)
65 jaar en ouder
65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

Leeftijd ≥ 18 jr

Op de wachtlijst voor totale schouderprothese, reversed schouderprothese of hemi-prothese

In staat om geschreven informed consent te geven

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Cognitieve beperkingen

Onvoldoende beheersing van de Nederlandse taal

Schoudervervanging naar aanleiding van een acute fractuur

Onderzoeksopzet

Opzet

Fase onderzoek:	N.V.T.
Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Enkelvoudig
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend
Doel:	Behandeling / therapie

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	24-04-2018
Aantal proefpersonen:	220
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	28-08-2017
Soort:	Eerste indiening
Toetsingscommissie:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6639
NTR-old	NTR6825
Ander register	MEC ZWH : 17-117 (niet WMO plichtig)

Resultaten