

Onderzoek beleving staaroperatie

Gepubliceerd: 10-04-2014 Laatste bijgewerkt: 13-12-2022

Primary Objective: Establishing the course of surgical fear, assessed by the surgical fear questionnaire at multiple time points, from one week before surgery until the day of surgery.

Secondary Objectives: • Establishing the convergent...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22026

Bron

NTR

Verkorte titel

SFQ at multiple time points

Aandoening

Cataract, surgical fear; staaroperatie, preoperatieve angst

Ondersteuning

Primaire sponsor: Maastricht University Medical Center (MUMC+)

Overige ondersteuning: Maastricht University, NWO VICI grant

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

SFQ scores measured at timepoints 1, 2, 3, and 4

Toelichting onderzoek

Achtergrond van het onderzoek

Validation of the Surgical Fear Questionnaire (SFQ) has recently been established. However, all studies used for validation applied the SFQ only at one single time point, and information on convergent validity of the SFQ, as a subjective instrument, with a biological index of fear is lacking.

The aim of this observational study is to establish the course of surgical fear, assessed by the SFQ at multiple time points and to establish the convergent validity of the SFQ with salivary cortisol and alpha amylase levels. Furthermore the patient preferences for preoperative treatment of surgical fear are assessed, and SFQ scores of the first and second cataract surgery are compared.

Primary outcome measure:

SFQ scores measured at one week before first surgery, the day before first surgery, the day of first surgery and the day before second surgery.

Secondary outcomes:

Salivary cortisol and alpha amylase levels, the NRS fear score, retrospective evaluation of SFQ score, preferences for surgical fear treatment, surgical recovery , and postsurgical pain.

Population:

Adult cataract surgery patients (N=102).

Doel van het onderzoek

Primary Objective:

Establishing the course of surgical fear, assessed by the surgical fear questionnaire at multiple time points, from one week before surgery until the day of surgery.

Secondary Objectives:

- Establishing the convergent validity of the SFQ with two biological indexes of stress/anxiety, salivary cortisol and salivary alpha amylase.
- Assessing patient preferences for preoperative treatment of surgical fear
- Comparing SFQ scores of the first versus the second cataract surgery.

Onderzoeksopzet

1. one week before first surgery
2. the day before first surgery
3. the day of first surgery
4. the day before second surgery
5. four weeks after (second) surgery

Onderzoeksproduct en/of interventie

Not applicable

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age > 18 years
- Elective cataract surgery (one or both eyes)
- Day surgery setting
- Waiting list > 1 week
- (Loco-)regional anesthesia
- Good command of Dutch language
- Informed consent
- ASA-classification I-III

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Cataract surgery of first eye already performed last year
- Illiteracy
- Cognitive impairment (as indicated in the medical record)
- General anesthesia
- Corticosteroid use (except inhaler)
- M. Cushing, Addison's disease, Hypo-/Hyperthyroid
- ASA-classification IV
- Participation in another clinical trial

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	13-02-2014
Aantal proefpersonen:	102
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	10-04-2014
Soort:	Eerste indiening

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	NL4253
NTR-old	NTR4491
Ander register	METC azM/UM : 13-4-098

Resultaten