Onderzoek beleving staaroperatie

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22026

Source
NTR

Brief title
SFQ at multiple time points

Health condition

Cataract, surgical fear; staaroperatie, preoperatieve angst

Sponsors and support

Primary sponsor: Maastricht University Medical Center (MUMC+)
Source(s) of monetary or material Support: Maastricht University, NWO VICI grant

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

• salivary cortisol measured at time points 1,2,3, and 5. At all time points three samples will be taken: morning after awakening, afternoon 15:00-16:00hrs, evening 20:00-21:00hrs. At time point 3, the second and third sample are collected in-hospital pre- and postoperatively.

• Salivary alpha amylase, measured at time point 3 in the same saliva sample used for cortisol determination.
• NRS (0-10) fear score. On the day of surgery, together with the salivary samples a one-item fear score will be assessed.
• Retrospective evaluation of own surgical fear measured at timepoint 3 post-operatively on a five-point Likert scale.
• Preferences for treatment of surgical fear, assessed at time point 5.
• Surgical recovery, assesed at timepoint 5 with the Global Surgical Recovery (GSR)Scale (0-100%). Also postoperative pain will be assessed with a NRS score (0-10).

Study description

Background summary

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).

Study objective

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.

Study design

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

Intervention

Not applicable

Contacts

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Eligibility criteria

Inclusion criteria

• 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

Exclusion criteria

• 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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-02-2014
Enrollment:	102
Type:	Anticipated

Ethics review

Positive opinion

Date:	10-04-2014
Application type:	First submission

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
NTR-new	NL4253
NTR-old	NTR4491
Other	METC azM/UM : 13-4-098

Study results