Inhibitory Functions as Predictors of Chronic Pain: a Pilot Study

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON38768

Source
ToetsingOnline

Brief title
Inhibition and chronic pain

Condition

- Gastrointestinal therapeutic procedures

Synonym
Postoperative; chronic pain

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universiteit Nijmegen
Source(s) of monetary or material Support: IASP (International Association for the Study on Pain;een non-profit organisatie)

Intervention

Keyword: Inhibition, Pain, Perioperative, Postoperative

Outcome measures

Primary outcome

The main study outcome parameter is the presence and severity of pain, assessed with visual analogue scales, 7 to 10 days after and three months after surgery. Preoperative endogenous inhibitory functions will form the predictors of acute and persistent postoperative pain and will consist of three different measurements: 1. cognitive inhibition as measured with the Stroop taks and with the Go/No-Go task, to measure interference control and prepotent response inhibition respectively; 2. Conditioned Pain Modulation (CPM) in order to examine the extent to which a painful stimulation (cold pressor test) inhibits to experience of another painful stimulation (second PPT and EPTT, compared to the first PPT and EPTT), and; 3. Placebo- and nocebo-suggestions, to examine the extent to which expectations inhibit (placebo) or facilitate (nocebo, by diminishing inhibitory functions) pain experience.

Secondary outcome

1. Quality of life as assessed with the SF-36

2. Distress and mood ratings as assessed with visual analogue scales.

Study description

Background summary

Chronic pain is a major cause of disability, affecting approximately 20% of the general population. Up until now, chronic pain remains a difficult to treat

condition. Our knowledge is particularly lacking regarding the mechanisms underlying the development of chronic pain. In this study, we will focus on the predictive value of endogenous inhibitory functions for the development of postoperative pain. These endogenous inhibitory functions refer to functions that are part of normal cognitive and pain control mechanisms. It has been shown that these functions predict experimental, acute, pain sensitivity in healthy volunteers; never have inhibitory functions been examined as predictors of chronic pain. The aim of the present study is to overcome this limitation, by examining the level of inhibitory functions in relation to the development of postoperative pain.
To examine this in detail, we will focus on three different forms of endogenous inhibition: 1. Cognitive inhibition as measured with cognitive tests, 2. Conditioned pain modulation as measured with the pain inhibits pain phenomenon, and 3. Placebo- and nocebo-like effects, in which the effect of suggestions on pain experience will be evaluated. These functions will be assessed pre-operatively in a sample of patients scheduled for pancreatic resection surgery for (pre)cancer. These patients normally do not report pain pre-operatively; incidence rates of postoperative pain are high, in that as much as 30-40% of these patients may develop persistent pain (PP) following surgery. This model is therefore suitable for identifying those at an increased risk for developing chronic pain.
Our hypothesis is that reduced pre-operative endogenous inhibitory functioning predicts the development of PP as well as a higher intensity of PP. In addition, it is expected that the different inhibition functions partially act in a complementary way, in that they uniquely predict part of the variance in postoperative pain.

Study objective

The primary objective is to examine the predictive value of several types of endogenous inhibitory functions for the risk and severity of acute and persistent pain after surgery. As primary outcome parameter, patients will be asked to keep a pain diary during three days, the first starting approximately 7 to 10 days after surgery (T1) and the second 3 months later (T2). In this diary, daily ratings of pain intensity will be recorded on visual analogue scales. The primary predictors consist of the three endogenous inhibitory functions: 1. Cognitive inhibition, which will be measured with computer tasks measuring respectively interference control and prepotent response inhibition; 2. Conditioned pain modulation, measured using a validated paradigm in which pressure pain threshold (PPT) and electrical pain threshold tolerance (EPTT) are first determined, followed by a cold pressor test (holding one*s hand in cold water) followed again by a PPT and EPTT measurement. An increase in the second PPT and EPTT indicates the presence of pain inhibitory functions, also referred to as diffuse noxious inhibitory controls (DNIC); 3. Placebo- and nocebo-suggestions, in which cues indicating low and high painful stimulation are followed by either a correct stimulus (respectively low and high stimulation) or an incorrect stimulus (respectively high and low stimulation).

A secondary objective is quality of life assessed with the SF -36. Next to the pain ratings, participants will perform daily indications of distress and mood.

Study design

A prospective pilot study in which the predictive value of several endogenous inhibitory functions for postoperative pain will be assessed.

Study burden and risks

All tests and methods that are used are non-invasive and not stressful for the patient. All cognitive tests and questionnaires are widely-used validated and reliable paper-pencil or computerized tasks. The CPM measurement and the placebo- and nocebo-like measurements will be based on validated protocols. The participant can work at his/her work pace, and if desired additional breaks will be taken. The preoperative testing will take approximately 1.5 hours; the two postoperative measurements will take approximately 45 minutes each.

Contacts

Public
Radboud Universiteit Nijmegen

Montessorilaan 3
Nijmegen 6500HE
NL
Scientific
Radboud Universiteit Nijmegen

Montessorilaan 3
Nijmegen 6500HE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Scheduled for pancreatic resection surgery for (pre)cancer

Exclusion criteria

- Inability to speak/understand the Dutch language.
- Severe psychiatric problems
- Neurodegenerative disorders
- Substance abuse
- History of stroke
- Previous major abdominal or thoracic surgery
- Current chronic pain condition

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-06-2014
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	22-10-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	04-07-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL44965.091.13