The development of secondary hyperalgesia after high frequency electrical stimulation (HFS) of the skin in patients with and without chronic postoperative pain after inguinal hernia repair.

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To identify the mechanism(s) of pain in patients with chronic pain after inguinal hernia repair.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Skin and subcutaneous tissue therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON34441

Source
ToetsingOnline

Brief title
Sec.hyperalgesia in patients with chronic pain after inguinal hernia repair

Condition

- Skin and subcutaneous tissue therapeutic procedures

Synonym
chronic discomfort, chronic pain

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: hyperalgesia, inguinal hernia, pain

Outcome measures

Primary outcome

The difference between post minus pre HFS measures regarding the subjective intensity (VAS) and the event-related potential amplitude compared between patients with chronic pain and patients without pain. The nature of pain will be classified using the DN4 (Douleur Neuropathique en 4 Questions).

Secondary outcome

To investigate the nature of the pain, i.e. whether it is of neuropathic origin or not. To document the presence of depressive symptoms. To document the amount of catastrophising. To document the quality of life .

Study description

Background summary

Persistent postoperative pain (pain that persist long after the initially surgical injury has healed) is a major social and medical problem because it significantly affects quality of life and is difficult to treat. The understanding of the underlying neurobiology is limited, but a fundamental underlying mechanism appears to be abnormal persistence and spread of central sensitisation, expressed as persistent and spreading hyperalgesia (i.e. increased pain sensitivity) in non-damaged tissues. Nerve damage due to the surgery seems to play a key role in this context. This is because nerve injury, apart from itself directly producing marked central sensitization, is particularly efficient at producing a pro-nociceptive state by depressing inhibitory descending modulation (disinhibition) and favouring the process of

descending facilitation. Both processes will result in more hyperalgesia in skin areas surrounding or remote from the surgical area. This study proposes to investigate the facilitating state accompanying chronic pain associated with nerve damage by using an experimental pain model (high frequency electric skin stimulation = HFS) to study the ease of inducing secondary hyperalgesia in patients with or without chronic pain after nerve-damaging inguinal surgery.

Study objective

To identify the mechanism(s) of pain in patients with chronic pain after inguinal hernia repair.

Study design

Observational study, mixed design (pre vs. post HFS, comparison between patients with and without chronic pain). All subjects will receive four trains of 20 nociceptive test stimuli quantified by simultaneous determination of ERPs and Visual Analogue Scale (VAS), with the conditioning stimulation (HFS) in between

Study burden and risks

The burden is small and consists of a visit to the UMC, having a paintest and filling in a few questionnaires. The total time occupied with the study per patient is maximal 3.5 hours.!

Contacts

Public
Universitair Medisch Centrum Sint Radboud

postbus 9101
6500 HB Nijmegen
NL
Scientific
Universitair Medisch Centrum Sint Radboud

postbus 9101
6500 HB Nijmegen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Presence of chronic pain as a result of inguinal hernia repair (local pain) for the experimental group
No pain aftere inguinal hernia repair for the control group
6 to 7 years after surgery (operated between April 2001 and March 2003)
Aged 18 - 65 year
Men
Ability to give informed consent
Ability to understand the research and follow the instructions during the experiment

Exclusion criteria

Presence or history of other neurological or major psychiatric diseases
Regular intake of medication affecting potentially brain function or EEG signal (e.g., psychopharmacological drugs; morphine, anti-psychotics, anti-depressives, anti-epileptica, benzodiazepines)
Regular legal or illegal drug intake
Any pre-existing type of chronic pain syndrome
No participation in other research

Study design

Design

Study type:	Observational non invasive

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2010
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	20-07-2010
Application type:	First submission
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	NL32573.091.10