Investigation of Pain and Anxiety in INterventional Radiology

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To set up a cohort of patients undergoing radiological interventions, which will serve as a platform for randomized evaluation of different pain and anxiety management strategies in order to improve on routine care by searching for a more effective...

Ethical review	Not approved
Status	Will not start
Health condition type	Therapeutic procedures and supportive care NEC
Study type	Observational non invasive

Summary

ID

NL-OMON45296

Source
ToetsingOnline

Brief title
iPAIN

Condition

- Therapeutic procedures and supportive care NEC

Synonym
Periprocedural pain

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Anxiety, Intervention, Pain, Radiology

Outcome measures

Primary outcome

The pain is measured using a numeric rating scale (NRS) and anxiety using the

Richmond agiation-sedation scale (RASS) during the intervention, as part of

standard clinical practice.

Secondary outcome

Not applicable.

Study description

Background summary

In interventional radiology, minimally invasive treatment options are increasing. However, these procedures can be painful or stressful to undergo. Pain varies substantially from easily manageable with subcutaneous infiltration to requiring full anesthesia. The unpredictable nature, in combination with the logistical issues associated with moderate and deep sedation or full anesthesia, leaves room for improved anesthetic care during interventional radiology procedures.

Study objective

To set up a cohort of patients undergoing radiological interventions, which will serve as a platform for randomized evaluation of different pain and anxiety management strategies in order to improve on routine care by searching for a more effective strategy for analgesia and/or anxiolysis from both patient and physician standpoint.

Study design

Observational, prospective cohort study, according to the *cohort multiple Randomised Controlled Trial* (cmRCT) design.

Study burden and risks

The burden of participation is minimal: Patient data will be collected from the medical records.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

In order to be eligible to participate in this study, a subject must undergo a radiological procedure. As pain or anxiety is highly variable, there is no a priori limitation to particular procedures.

Exclusion criteria

- Less than 18 years of age;
- Not being capable of giving informed consent.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	2000
Type:	Anticipated

Ethics review

Not approved

Date:	11-04-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL60591.041.17