Validation of the Breakthrough Assessment Tool

No registrations found.

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

Summary

ID

NL-OMON23176

Source
Nationaal Trial Register

Health condition

Cancer, pain, breakthrough pain

Sponsors and support

Primary sponsor: Erasmus Medical Center
Source(s) of monetary or material Support: Erasmus Medical Center, Innovatiefonds

Intervention

Outcome measures

Primary outcome

Contruct validity of the third questionnaire compared to the first questionnaire

Secondary outcome

- pain evaluation

- face and content validity

- reliability

- responsiveness to change

- acceptability

Study description

Background summary

In patients with cancer, pain is one of the most frequent and feared symptoms. Pain can interfere with all aspects of daily life and pain intensity is an important component of patients□f quality of life. Usually, patients experience fluctuations in their pain intensity. In most patients, pain has continuous and a variable components. The continuous component is mostly referred to as □ebackground pain□f. The variable component of pain is usually described as □ebreakthrough pain□f. Successful management of breakthrough pain depends on adequate assessment, appropriate treatment and adequate reassessment. A number of tools have been developed for the assessment of cancer□]related pain. These tools mainly focus on the background pain and most tools provide only little information about the breakthrough pain. Recently, a new assessment tool has been developed for daily practice, the Breakthrough pain Assessment Tool (BAT). The BAT was validated in a group of 100 English cancer patients. After this first validation in an English population of cancer patients (in all stages of the disease), this assessment tool for breakthrough pain seems to be a validated and reliable
questionnaire for daily practice. Therefore, the BAT is the preferred breakthrough assessment tool to be used in the Netherlands.

In this study we will:

1. Translate the BAT into Dutch according the EORTC translation guidelines

2. Validate the BAT□]Dutch language version in cancer patients with breakthrough pain

Study objective

The Dutch version of the Breakthrough pain Assessment Tool (BAT) is a valid and reliable questionnaire to measure differences in breakthrough pain in patients with cancer

Study design

T0 = at baseline

T1 = 24 hrs after baseline

T2 = 1 week after baseline

T3 = 1 week after T1

Intervention

all patients complete the study questionnaire 4 times within a two week timeframe.

Contacts

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Eligibility criteria

Inclusion criteria

1. patients with a pathologically confirmed diagnosis of cancer

2. patients must be 18 years of age or older

3. pain due to cancer or its treatment

4. patients took regular scheduled analgesia in the previous week

5. patients considered to have breakthrough pain according a 'clinical expert'

6. patients must have taken at least one dose of 'rescue' medication for a breakthrough episode in the previous week

7. cognitive status sufficient for accurate completion of the study

8. ability to provide written informed consent

Exclusion criteria

1. patients who cannot understand the intent of the study, in their physician's estimation

2. patients whose performance status is felt to be too poor to allow them to complete the survey

3. patients who refuse to participate

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2016
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

Date:	01-03-2018
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	NL6884
NTR-old	NTR7062
Other	: MEC-2013-056

Study results

Summary results
n/a