Effects and side effects of strong-acting opioids for the treatment of cancer-related pain: a study of the role of differences in metabolism (degradation) of the medicine and differences in genes

No registrations found.

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

Summary

ID

NL-OMON29058

Source
NTR

Health condition

Cancer-related pain
Strong-acting opioids
Pharmacogenetic(s)
Pharmacokinetics
Opioid rotation
Pain control
Side effects

Kanker gerelateerde pijn
sterk werkende opioiden
Farmacogenetica
Farmacokinetiek
Opioid rotatie
Pijncontrole
Bijwerkingen

Sponsors and support

Primary sponsor: Erasmus MC Cancer Institute, Rotterdam, the Netherlands
Source(s) of monetary or material Support: Erasmus MC Mrace Grant
ZonMw 11510014

Intervention

Outcome measures

Primary outcome

- Are variations in pharmacogenetics and/or pharmacokinetics related to insufficient pain control and/or the occurrence of intolerable side effects?
- To study the role of demographic and clinical factors on outcome of treatment
- To study how the factors mentioned above affect the outcome of opioid rotation

Secondary outcome

-

Study description

Background summary

This is a study to investigate the role of demographic and clinical factors, pharmacokinetic and pharmacogenetic variations on the outcome of treatment with strong-acting opioids for cancer related pain. Also, factors influencing the outcome of opioid rotation are studied. Based on these factors recommendations will be made which will validated in the second phase of the study

Study objective

Variations in pharmacogenetics and or pharmacogenetics are related to clinical outcome of treatment with strong-acting opioids for cancer-related pain

Study design

Inclusion of patients until the end of 2014
Start validation phase per 1-1-2015

Intervention

Treatment is given according to physician's choice
Blood samples drawn for pharmacogenetic analysis in all patients
Blood samples drawn for pharmacokinetic analysis in patients who consent only

Contacts

Public
P.O. Box 5201, 3008 AE Rotterdam, The Netherlands
A, Oosten
Groene Hilledijk 301, room G4-73
Rotterdam 3075 EA
The Netherlands
+31 10 704 19 06
Scientific
P.O. Box 5201, 3008 AE Rotterdam, The Netherlands
A, Oosten
Groene Hilledijk 301, room G4-73
Rotterdam 3075 EA
The Netherlands
+31 10 704 19 06

Eligibility criteria

Inclusion criteria

Hospitalized patients treated with strong-acting opioids for moderate to severe cancer related nociceptive pain.
Starting treatment with strong-acting opioids or needing adjustment of current treatment

Exclusion criteria

Estimated duration of hospitalisation < 72 hours

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):	01-01-2010
Enrollment:	350
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-01-2014
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	NL4225

Register	ID
NTR-old	NTR4369
Other	EudraCT Number: 2009-013022-16 : ZonMw 11510014

Study results

Summary results
Not yet