A multicentre outcome research in daily clinical practice concerning the prevention of acute and delayed nausea and vomiting after chemotherapy: an outcome research.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27981

Source
Nationaal Trial Register

Brief title
N/A

Health condition

chemotherapy induced nausea and vomiting, adherence to guidelines, efficacy antiemetics, quality of life.

chemotherapie geinduceerde misselijkheid en braken, opvolgen behandelrichtlijnen, effectiviteit anti-emetica, kwaliteit van leven

Sponsors and support

Primary sponsor: Hospital Pharmacy Medical Centre Alkmaar
Ziekenhuisapotheek Medisch Centrum Alkmaar
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

1. To make an inventory on the antiemetic policy in several peripheral hospitals;

2. To make an inventory on the effectiveness of these antiemetic policies.

Secondary outcome

1. What is the difference in antiemetic policies used in several peripheral hospitals?

2. Do these antiemetic policies correspond with evidence based guidelines?

3. Is aprepitant used in high emetogenic chemotherapy treatment or moderate emetogenic chemotherapy treatment?

4. What is the incidence of acute and delayed nausea and vomiting in chemotherapy treatment and does this correspond with literature?

5. Can differences in effectiveness be explained by differences in patient characteristics, chemotherapy and/or antiemetic policy?

Study description

Background summary

Nausea and vomiting are still two of the most serious side effects in chemotherapy treatment, even after the introduction of 5HT3 antagonists. The effectiveness of antiemetics used in the prevention of nausea and vomiting is not sufficient according to literature. Especially the prevention of delayed nausea and vomiting is difficult.

This study uses self reported sides effects including nausea and vomiting by means of a patient diary which also includes a quality of life assessment.

This outcomes research provides insight into the effectiveness of antiemetic policies in daily practice, in several peripheral hospitals.

Study objective

1. Adherence to guidelines/protocols is unsatisfactory;

2. No regimen is superior in the proportion of patients with minimal or no impact of emesis on daily living as measured using the Functional Living Index-Emesis questionnaire.

Study design

N/A

Intervention

This study uses self reported sides effects including nausea and vomiting by means of a patient diary which also includes a quality of life assessment.

Contacts

Public
Medical Centre Alkmaar, Hospital Pharmacy
P.O. Box 501
H.J. Doodeman
Alkmaar 1800 AM
The Netherlands
+31 72-5483591
Scientific
Medical Centre Alkmaar, Hospital Pharmacy
P.O. Box 501
H.J. Doodeman
Alkmaar 1800 AM
The Netherlands
+31 72-5483591

Eligibility criteria

Inclusion criteria

1. Chemotherapy naive patients receiving chemotherapy.

Exclusion criteria

1. Life expectancy less than three months;

2. Lack of basic proficiency in Dutch;

3. Age below 18;

4. Pregnancy;

5. Psychological illness.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-04-2005
Enrollment:	600
Type:	Actual

Ethics review

Positive opinion

Date:	19-06-2007
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	NL974
NTR-old	NTR1001
Other	: P05.0473L
ISRCTN	ISRCTN55375237

Study results

Summary results
N/A