

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

Submission date 16/07/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 16/07/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 27/10/2021	Condition category Signs and Symptoms	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

P05.0473L, NL974 (NTR1001)

Study information

Scientific Title

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

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the local medical ethics committee (Medisch Ethische Toetsingscommissie Noord-Holland [METC Noord-Holland]) on the 12th April 2005 (ref: M05-011).

Study design

Multicentre, observational, outcomes research study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet**Health condition(s) or problem(s) studied**

Quality of life and chemotherapy induced nausea and vomiting

Interventions

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.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. To make an inventory on the anti-emetic policy in several peripheral hospitals
2. To make an inventory on the effectiveness of these anti-emetic policies

Secondary outcome measures

1. What is the difference in anti-emetic policies used in several peripheral hospitals?
2. Do these anti-emetic 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 anti-emetic policy?

Overall study start date

15/04/2005

Completion date

01/09/2007

Eligibility

Key inclusion criteria

Chemotherapy naive patients receiving chemotherapy.

Participant type(s)

Patient

Age group

Adult

Sex

Not Specified

Target number of participants

600

Key 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

Date of first enrolment

15/04/2005

Date of final enrolment

01/09/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

Medical Centre Alkmaar

Alkmaar

Netherlands

1800 AM

Sponsor information

Organisation

Medical Centre Alkmaar (Medisch Centrum Alkmaar) (The Netherlands)

Sponsor details

Hospital Pharmacy

Alkmaar

Netherlands

1800 AM

Sponsor type

Hospital/treatment centre

Website

http://www.mca.nl/webframe/modules/mod_webcontroleur/voorkant.php?id=5

ROR

<https://ror.org/04vccmr34>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Medical Centre Alkmaar (Medisch Centrum Alkmaar) (The Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration