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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

Registration date
16/07/2007

Overall study status
Completed

Last Edited
27/10/2021

Condition category
Signs and Symptoms

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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