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Effects of a pain consult and patient education and monitoring: a prospective study in oncology patients

Submission date	Recruitment status	[ ] Prospectively registered
28/04/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/04/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/08/2009	Signs and Symptoms	[ ] 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

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR613; EMC 2005 - 257

Study information

Scientific Title

Study objectives
It is hypothesised that a pain consult at the specialized pain clinic in combination with Patient Education Program is more effective in reducing average pain intensity compared to a pain consult alone. A pain consult at the specialized pain clinic is more effective in reducing average pain intensity compared to standard care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Cancer pain

Interventions
1. Standard care
2. Second opinion pain consult at the specialist pain clinic
3. Second opinion pain consult combined with Pain Education Program and monitoring by nurse specialists

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Average pain reduction measured by numeric rating scale during the study period.

Secondary outcome measures
Effect of the interventions after 2, 4 and 8 weeks on:
1. Adherence to ATC analgesics
2. Worst pain reduction
3. Average pain reduction
4. Present pain reduction
5. Proportion of patients with clinically relevant pain reduction
6. Pain interference
7. Quality of life
8. Reduction of side effects
9. Adequacy of pain treatment
10. Pain knowledge

Overall study start date
01/02/2006

Completion date
31/12/2007

Eligibility

Key inclusion criteria
1. Cancer-related pain or cancer treatment related pain for at least two weeks
2. Nociceptive pain
3. Average pain intensity score of 4 or more
4. Accessibility by telephone
5. A life expectancy of at least three months
6. Informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
165

Key exclusion criteria
1. Neuropathic pain
2. Residing in nursing home or retirement home
3. Pain not treated with oral medication
4. Radiotherapy in the past two weeks

Date of first enrolment
01/02/2006

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus Medical Center
Rotterdam
Netherlands
3008 AE

Sponsor information

Organisation
Erasmus Medical Center (Netherlands)

Sponsor details
P.O. Box 2040
Rotterdam
Netherlands
3000 CA

Sponsor type
University/education

ROR
https://ror.org/018906e22

Funder(s)

Funder type
University/education

Funder Name
Erasmus Medical Center (Netherlands)

Alternative Name(s)
Erasmus Medical Center, Erasmus MC, Erasmus Universitair Medisch Centrum, Erasmus University Medical Center, Universitair Medisch Centrum Rotterdam, Erasmus Universitair Medisch Centrum Rotterdam, EMC

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration