Palliative care for patients with irresectable or recurrent cancer of the upper gastrointestinal tract: a randomized study

Submission date	Recruitment status No longer recruiting	Prospectively registered		
19/07/2006		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
19/07/2006	Completed Condition category	[X] Results		
Last Edited		[] Individual participant data		
08/01/2021	Cancer			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

 ${\bf Clinical Trials. gov\ number}$

Secondary identifying numbers

MEC-2005-176, NL628, NTR687

Study information

Scientific Title

Palliative care for patients with irresectable or recurrent cancer of the upper gastrointestinal tract: a randomized study

Acronym

PACT study.

Study objectives

Does nurse-led follow-up at home lead to improved quality of life and satisfaction and a reduction in costs compared to medical follow-up at the outpatient clinic, without compromising the medical condition of patients?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled, parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Esophageal, pancreatic or hepatobiliairy cancer

Interventions

Nurse-led follow-up at home at two-weekly and later monthly intervals until month 13 or death versus medical follow-up at the outpatient clinic at one month and thereafter every two months until month 13 or death

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Quality of life questionnaires

Secondary outcome measures

Patient satisfaction (questionnaire) costs

Overall study start date

01/06/2006

Completion date

01/01/2009

Eligibility

Key inclusion criteria

- 1. Patients with irresectabel or recurrent esophageal cancer, pancreatic cancer or hepatobiliary cancer, for whom no curative treatment options are available
- 2. Informed consent

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

150

Key exclusion criteria

- 1. Not able to understand or read the Dutch language
- 2. Undergoing treatment with chemotherapy or radiotherapy or a combination

Date of first enrolment

01/06/2006

Date of final enrolment

01/01/2009

Locations

Countries of recruitment

Netherlands

Study participating centre Erasmus MC - University Medical Center Rotterdam Rotterdam Netherlands 3000 CA

Sponsor information

Organisation

Health Care Research Program Erasmus MC 2003 (The Netherlands)

Sponsor details

Erasmus MC - University Medical Center Rotterdam Department of Gastroenterology and Hepatology Room HS 512 P.O. Box 2040 Rotterdam Netherlands 3000 CA

Sponsor type

University/education

Funder(s)

Funder type

University/education

Funder Name

Erasmus Medical Center

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2014	08/01/2021	Yes	No