

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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21003

Source

NTR

Brief title

PACT study.

Sponsors and support

Primary sponsor: Erasmus MC - University Medical Center Rotterdam
Dept. Gastroenterology & Hepatology
Dr. Molewaterplein 40
3015 GD Rotterdam

Intervention

Outcome measures

Primary outcome

Quality of life (questionnaires).

Secondary outcome

Patient satisfaction (questionnaire) costs.

Study description

Background summary

For patients with irresectable of recurrent esophageal-, pancreatic- or hepatobiliary cancer, no curative treatment options are available. The median survival for this group is only 2-10 months. The treatment aim in the palliative phase is to improve the quality of life of patients and their family, through the prevention and relief of suffering by means of the identification and treatment of pain and other physical, psychosocial and spiritual problems. The high degree of physical and psychological problems in this phase suggest a need for close monitoring and support.

Presently, patients in the palliative phase of their disease visit the outpatient clinic for medical follow up. The frequency is usually low with a mean of every 8 weeks. These visits to the hospital are a burden for the majority of patients. We hypothesized that nurse-led follow up at home could be a valuable alternative for these patients. This study will evaluate nurse-led follow up for palliative GI cancer patients by home visits. Outcome will be compared with the usual medical follow up at the outpatient clinic. Outcome measures are: quality of life, patient satisfaction and costs.

Study objective

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

Intervention

Nurse led follow up at home at 2-weekly and later monthly intervals until month 13 or death versus medical follow up at the outpatient clinic at 1 month and thereafter every 2 months until month 13 or death.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with irresectable of recurrent esophageal-, pancreatic- and hepatobiliary cancer, for whom no curative treatment options are available;
2. Informed consent.

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-06-2006
Enrollment:	150
Type:	Anticipated

Ethics review

Positive opinion	
Date:	19-05-2006
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	NL628
NTR-old	NTR687
Other	: MEC-2005-176
ISRCTN	ISRCTN86515732

Study results

Summary results

N/A