Towards a practice-based approach to prevent burdensome treatment: interviewstudy among cancer patients

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Metastases
Study type	Observational non invasive

Summary

ID

NL-OMON35598

Source
ToetsingOnline

Brief title
Adequate treatment at the end of life

Condition

- Metastases

Synonym
incurable cancer, metastatic breast and mamma cancer

Research involving
Human

Sponsors and support

Primary sponsor: Onze Lieve Vrouwe Gasthuis
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Cancer, Chemotherapy, End-of-life decision-making, Quality of life

Outcome measures

Primary outcome

The primary parameters are patients* experiences with a conversation about

their approaching death and their attitudes and wishes with respect to care and

treatment at the end of life.

Secondary outcome

Secondary outcomes:

- Patient*s age

- Sex

- Disease history

- Number of withdrawals in the study with accompanying reason

Study description

Background summary

The progress in the treatment of many cancers is substantial. With a growing arsenal of new, more effective treatment options, deciding about treatment at the end of life has become a delicate process. In general, when a curative goal has become unfeasible, the goal of treatment is to delay and relieve tumor-related symptoms. Yet, these goals may sometimes go together with serious side-effects, such as nausea and fatigue. At present, possible overuse of chemotherapy at the end of life is widely debated in the medical arena: To what extent can chemotherapy be considered in the patient*s best interest?

Previous research shows that physicians and nurses seldom bring up the last phase of life - in the most broadest sense - during consultations because they regard such a conversation as a *contradiction in terms*: they seem to

associate such conversations with the forgoing of treatment (mostly chemotherapy). This study also showed that physicians realized that late initiations of end-of-life discussions (and possible withholding of further treatment) would shorten their patients* time to accept death and to say farewell. Because physicians did not want to take away the patient*s hope, by confronting them with death, they seem to focus on further treatment in their communication.

Nurses, however, sometimes said that they considered speaking about death and dying - in itself - confronting and therefore difficult to broach. They further more frequently seemed to question whether further treatment could be considered in the patient*s best interest. The few physicians and nurses who spoke with their patients about the last phase of life said that it opened up the discussion and the quality of the communication.

Very recently, a discussion about the benefits of having an early discussion about the end of life started up in the Netherlands. It is however unclear what exactly the patients* wishes are in the last phase of life.

Study objective

The primary objectives of this study are:

1. To assess the ideas and attitudes of patients with metastatic cancer about continuation of (another line of) chemotherapy.

2. To assess how patients experience a discussion about the last phase of life and in particular a discussion about their approaching death.

3. To assess patients* needs and wishes with respect to the last phase of life

And by means of this exploration (secondary objective):

4. To develop a checklist that informs, motivates and supports healthcare professionals during the treatment decision-making and to assist them when they have difficult ethical questions.

Study design

This is an observational study in which we would like to depict the attitudes and experiences of patients with metastatic cancer about their care and treatment wishes at the end of life as well as their thoughts about having a discussion about their approaching death.

By interviewing cancer patients who receive (palliative) chemotherapy, we also would like to explore the role of physicians and nurses in the treatment

decision-making and we will have short additional talks with the physician and nurse afterwards [not applicable for this application].

We will interview approximately 20 patients. In about 10 patients, the nurse will have an additional talk about patients' attitudes and wishes about the end of life before the patient's consultation with the treating physician.

By comparing a group of patients who has had an additional talk with a nurse with a group of patients who did not have such a talk, we will evaluate how they experienced such conversations with nurses. This is a well-established method in qualitative research.

Patients will be split up in two different groups:

- The first patient that will be recruited, will be interviewed after the patient and physician made a decision about the next line of chemotherapy (group 1).
- The second patient that will be recruited, will have an additional talk with the nurse first about care and treatment in the last phase of life. After the consultation with the physician, the patient will be interviewed.
- The third patient will be placed in group 1, the fourth patient in group 2, etcetera.

Study burden and risks

Every interview will last approximately 45-60 minutes which could be considered a burden of the study. However, such interviews can be worthwhile for patients also especially because the interviewer is experienced in perfroming interviews in the field of end-of-life decision-making.

Patients* experiences are essential for the development of this checklist. The potential burdens are therefore in accordance with the (scientific) benefits of the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Adult patients who are capable to decide whether they are willing to participate in the study (e.g. being competent)

Exclusion criteria

Patients who are unable to speak the Dutch language

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-05-2012
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	07-11-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
CCMO	NL38186.100.11