Patient informed choice between palliative chemotherapy and best supportive care: who wants it?

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Aim of the study: To settle this debate, a decision aid is developed and presented to patients with metastatic disease, and its effects are assessed. The decision aid gives information on side-effects and prognosis of the treatments. We will address...

Ethical review	Approved WMO
Status	Pending
Health condition type	Endocrine neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON30246

Source
ToetsingOnline

Brief title
Who wants to be fully informed?

Condition

- Endocrine neoplasms benign

Synonym
patients with metastases

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Nederlandse Kanker Bestrijding

Intervention

Keyword: Patient Informed Choice, Patient-physician communication, Psychosocial research, Shared Decision Making

Outcome measures

Primary outcome

Number of information items requested by the patient

Secondary outcome

Well-being and psychological variables related to decision making

Study description

Background summary

Background: Patients with cancer rank information about risks and prognosis higher than other information needs. This information empoweres patients to be involved in their treatment decisions. Decision aids are effective tools to impart such information. Such aids are designed to help patients make specific and deliberative choices among options by providing information about the relevant options and outcomes. Some authors question this approach in the non-curative setting. Participation in treatment decisions are known to decline with increasing age and with the severity of the disease. Patients with cancer may become emotionally unstable, and this may decrease the uptake of information. These arguments are thought to be especially relevant for patients with a bad prognosis, e.g., patients with metastases. In contrast, other research on decision aids has shown that, from the patient perspective, decision aids are beneficial without causing harm, also for patients with cancer. In practice, clinicians may vary the amount of information based on their judgement of the patient. Thus there is a continuing debate on the desirability of informing patients with cancer and thereby involving them in their own care process.

Study objective

Aim of the study: To settle this debate, a decision aid is developed and presented to patients with metastatic disease, and its effects are assessed. The decision aid gives information on side-effects and prognosis of the treatments. We will address the following questions: 1a) Do these patients want to be informed about the treatment options, and specifically about their

prognosis? 1b) Which factors determine whether or not these patients want to be informed? 2) Can the medical oncologist judge whether or not the patient wants the risk information? 3) What is the effect of the decision aid on patient outcomes (well-being, information and decision related outcomes, treatment choice) compared to usual care?

Study design

Plan of investigation:
Patients are randomised between involvement (I) or usual care (II).
I: Involvement group. Questions 1 and 2 are studied using a decision aid as an intervention. A literature study will be undertaken to compare best supportive care and palliative chemotherapy. The results will be used to develop the decision aid. Patients with distant metastases or loco-regional recurrence after primary breast or colon cancer (N=150), who face the choice between first line palliative chemotherapy or best supportive care, are eligible and included prospectively. After the first consultation, the oncologist will judge whether the patient wants to be informed (question 2). In a consecutive face-to face interview with all patients, a research nurse will deliver the decision aid using a step-by-step procedure. Information about side-effects is given first. Information on prognosis is offered and delivered upon request. The number of information items desired by the patient is recorded. This, the information acceptance, is the main outcome measure, used to answer questions 1a and 1b. At baseline, 1 week before the interview, socio-demographic data, and psychological predictors, believed to predict information acceptance, are obtained by self-report questionnaires. Psychological predictors are e.g. cancer worries, mental adjustment to cancer, information preferences, and decision style preferences. After the interview, and two months later, we collect data on well-being, information and decision related outcomes, and treatment choice.

II: Usual Care group. 100 patients are approached, who will receive care as usual. Identical self -report questionnaires will be sent at the same time moments. By comparing the Usual Care with the Involvement group, question 3 is answered.

Intervention

The decision aid is delivered by a research nurse immediately after the visit with the medical oncologist, in which second line palliative chemotherapy is offered. The decision aid explains the two treatment options chemotherapy and best supportive care in detail, resulting in a strongly structured interview. Patients receive a general introduction about the benefits and risks of chemotherapy and best supportive care. The nature of all possible outcomes, (e.g. hair loss, nausea) is discussed taking into account factors that affect daily living.

Next, an overview of the two treatment options is presented. For each option, numerical risk information regarding the side-effects and prognosis (response rate, progression-free and overall survival) is available but not necessarily provided. Risk information is given in numeric format and using visual aids.
The risk information for both options will be given in a step-by-step procedure, starting with the information on side-effects, and followed by information on response chances, progression-free survival , and finally information on survival. Risk information on the side-effects of both options is given to all patients. After this information is provided, patients are asked whether they considered this information desirable. Next, patients are asked if they desire additional information on progression free survival for both options, to be delivered in a similar format. If desired , this information is provided. Finally this procedure is repeated for information on overall survival for both options. Thus our primary outcome, information acceptance, is assessed: it can range from zero to three, where zero corresponds with no information desired, and three corresponds with information desired for the side-effects, progression free, and overall survival. Reasons in favour and against acceptance are collected using open interview techniques. The provided information is also made available in a brochure, that can be taken home. Of course, the information in the brochure is tailored to the information desires of the patient.

Study burden and risks

All patients: 3 questionnaires of 40 minutes
Involvement-group: an interview (40 minuten) for presenting the decision aid and collecting the primary outcome measure

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

Patients with distant metastases or loco-regional recurrence after primary breast or colon cancer are eligible, if they face the choice between second line palliative chemotherapy or best supportive care.

Exclusion criteria

Exclusion criteria are labile personality structure, as assessed by the physicians, and a Karnofsky lower than 60.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2006
Enrollment:	170
Type:	Anticipated

Ethics review

Approved WMO
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL11011.091.06