Patient informed choice between palliative chemotherapy and best supportive care.

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1. 70% of patients will want risk information on the treatment options including prognosis; 2. Medical oncologists face difficulties while trying to judge which patients want the risk information?; 3. Effects of decision aid are positive.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24043

Bron
NTR

Verkorte titel
N/A

Aandoening

Paliative chemotherapy.

Ondersteuning

Primaire sponsor: P.Stalmeier, N. Ottevanger, P. de Mulder
Overige ondersteuning: Dutch Cancer Society, Amsterdam, the Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Risk information acceptance.

Toelichting onderzoek

Achtergrond van het onderzoek

Background:

Patients with cancer rank information about risks and prognosis higher than other information needs. This information empowers 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.

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:

1.a. Do these patients want to be informed about the treatment options, and specifically about their prognosis?;

1.b. 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?

Plan of investigation:

A literature study will be undertaken to compare best supportive care and second-line palliative chemotherapy. The results will be used to develop the decision aid. Patients with advanced colorectal, breast, or ovarian cancer, who have started treatment with first-line palliative chemotherapy and upon disease progression will be faced by the choice regarding second-line palliative chemotherapy, will be included. The oncologist will judge whether the patient wants to be informed (question 2). Patients will be sent a baseline questionnaire (t1) to collect sociodemographic data, and psychological predictors, believed to predict information acceptance (question 1b). Psychological predictors are e.g. cancer worries, mental adjustment to cancer, information preferences, and decision style preferences. When disease progression is diagnosed, randomization is performed to determine whether a patient will receive usual care (n=70) or usual care plus the decision aid (n=100). The decision aid is delivered by a nurse 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, 1b, and 2. To evaluate the effect of the decision aid (question 3), two follow-up questionnaires will be sent to all patients, one week (t2) and three months (t3) after the treatment choice.

Doel van het onderzoek

1. 70% of patients will want risk information on the treatment options including prognosis;

2. Medical oncologists face difficulties while trying to judge which patients want the risk information?;

3. Effects of decision aid are positive.

Onderzoeksopzet

Baseline questionnaire is during or after:

1st line chemotherapy treatment;

2nd questionnaire is 1 week after decision aid;

3rd questionnaire is 3 months after decision aid.

Onderzoeksproduct en/of interventie

Decision Aid lasting about 35 minutes.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients with distant metastases or loco-regional recurrence after primary breast, colon, or ovarian cancer are eligible, if they are treated or have been treated with first line palliative chemotherapy.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-01-2007
Aantal proefpersonen:	170
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	02-11-2007
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1080
NTR-old	NTR1113
Ander register	: KUN 2005-3465
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A