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A partnership on research priorities for patients with advanced cancer

Submission date 10/07/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 04/08/2015	**Overall study status** Completed	
Last Edited 06/11/2019	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims

There is a risk of discrepancy between what patients with advanced cancer and their relatives think are unanswered questions and what is the actual subject of research. The aim of this study is to challenge conventions by inviting patients with life-threatening cancer, their relatives and patient organisations to join forces with clinical specialists and researchers in order to identify, discuss and prioritise issues for future research.

A steering group will monitor the development of the project, help to validate research issues and provide inspiration for future developments. Establishing a partnership between patients, relatives, clinical specialists and researchers can potentially open the door to new perspectives within Danish research. This initial study could lead to a larger international research programme that includes several populations diagnosed with life-threatening cancer.

Who can participate?

Adult patients with brain tumour or with acute leukaemia, relatives, representatives from relevant patient organisations and specialists. Participants will be selected according to specific criteria and receive an invitation.

What does the study involve?

A series of focus group interviews (FGI).

What are the possible benefits and risks of participating?

Not applicable – this is a qualitative study.

Where is the study run from?

The steering group consists of representatives from the hospital management at Rigshospitalet (Copenhagen), the Danish Cancer Society, patient organisations, the Danish Research Centre for Patient Support and Empowerment in the Capital Region of Denmark, the University Hospitals' Center for Health Research (UCSF), the University of Copenhagen and the Section of Acute Pain Management and Palliative Medicine at Rigshospitalet.

When is the study starting and how long is it expected to run for?

May 2015 to April 2016.

Who is funding the study?
Danish Cancer Society

Who is the main contact?
Mrs Karin Piil

Contact information

Type(s)
Scientific

Contact name
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Study information

Scientific Title
Supportive care, palliation and quality of life for patients with life-threatening cancer and their relatives: a partnership on research priorities

Study objectives
There is a risk of discrepancy between what the patients with advanced cancer and their relatives experience as important unanswered questions and those which are actually researched. This pilot study challenges the conventional research process by inviting patients with life-threatening cancer, their relatives and patient organisations to join forces with clinical specialists and researchers to identify, discuss and prioritise issues for future research. The main focus of this project is supportive care and palliation as well as Health-related quality of life (HRQoL) in two patient groups with life-threatening illnesses (neuro-oncologic and malignant hematological diseases) and their families.

Ethics approval required
Old ethics approval format

Ethics approval(s)

This study has been registered by the Danish Data Protection Agency (file # RH-2015-106, 03871) and will be carried out in accordance with the Declaration of Helsinki. According to the Research Ethics Committee approval is not needed (file # H-15001485).

Primary study design
Observational

Study design
Qualitative study involving four focus group interviews (FGIs) for each included disease and treatment trajectory

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Advanced cancer

Interventions
Two separate groups will be recruited for the FGIs:
1. Ten brain tumour patients and ten relatives together with one representative from a brain tumour patient organisation
2. Ten patients with acute leukaemia, ten relatives and one representative from the patient support organisation for lymphoma and leukaemia.

Six clinical specialists within neuro-oncology/surgery and six clinical specialists within hematology are also invitede for FGI.

Three separate, parallel FGIs will be conducted with patients, relatives and specialists respectively. They will serve to define areas, and a fourth follow-up FGI will bring together three representatives from each group to validate and prioritise these areas. A representative from the relevant patient organisation will participate in the FGIs, both with the patients and with the relatives.The research issues that are not sufficiently illuminated by existing research will be presented at this FGI with a view to validating and prioritising them.

Intervention Type
Other

Primary outcome(s)
1. To establish meaningful cooperation between patients, relatives, specialists and researchers to identify, discuss and prioritise future research fields with a view to strengthening supportive care, palliative care and HRQOL including symptom management during and after the course of the disease and treatment
2. To examine existing literature on the identified fields to determine research relevance

Key secondary outcome(s)
To disseminate the findings and methods in a Danish context

Completion date
30/04/2016

Eligibility

Key inclusion criteria
Two separate groups will be recruited for the FGIs:
1. Ten brain tumour patients and ten relatives (not dyads) together with one representative from a brain tumour patient organisation
2. Ten patients with acute leukaemia, ten relatives one representative from the patient support organisation for lymphoma and leukemia (LyLe).

Participants must be a minimum of 18 years of age, have a Karnofsky Performance Status (KPS) of ≥ 60 and speak and understand Danish. Patients must have undergone at least two rounds of chemotherapy having experiences as a patient undergoing oncological treatment.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Karnofsky Performance Status (KPS) of < 60
2. Under 18 years of age

Date of first enrolment
15/08/2015

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Denmark

Study participating centre
Rigshospitalet, University of Copenhagen
Denmark
2100

Study participating centre
The University Hospitals Center for Health Research (UCSF) and Center for Integrated Rehabilitation of Cancer Patients (CIRE)
Denmark
2100

Sponsor information

Organisation
Rigshospitalet, University of Copenhagen UCSF 9701

ROR
https://ror.org/03mchdq19

Funder(s)

Funder type
Charity

Funder Name
Kræftens Bekæmpelse

Alternative Name(s)
Danish Cancer Society, The Danish Cancer Society, DCS

Funding Body Type
Government organisation

Funding Body Subtype
Associations and societies (private and public)

Location
Denmark

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available as they consist of sensitive and personal information

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2019	24/01/2019	Yes	No
Protocol article	protocol	24/05/2016		Yes	No