

# A partnership on research priorities for patients with advanced cancer

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| <b>Submission date</b><br>10/07/2015   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>04/08/2015 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results            |
| <b>Last Edited</b><br>06/11/2019       | <b>Condition category</b><br>Cancer               | <input type="checkbox"/> Individual participant data   |

## 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**  
Mrs Karin Piil

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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
Nil known

## 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).

### **Study design**

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

### **Primary study design**

Observational

### **Secondary study design**

Qualitative study

### **Study setting(s)**

Hospital

### **Study type(s)**

Quality of life

### **Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

### **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 invited 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 measure**

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

### **Secondary outcome measures**

To disseminate the findings and methods in a Danish context

### **Overall study start date**

01/05/2015

### **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  $\geq 60$  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

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

### **Target number of participants**

10 brain tumour patients and 10 relatives together with one representative from a brain tumour patient organisation, and 2) ten patients with acute leukemia, ten relatives and one representative from the patient support organisation for lymphoma and leukemia.

**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

**Sponsor details**

Blegdamsvej 9,

Copenhagen

Denmark

2100

+45 (0)3545 3545

rigshospitalet@rh.regionh.dk

**Sponsor type**

Hospital/treatment centre

**Website**

www.rh.dk

**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**

**Publication and dissemination plan**

The results papers will be published in December 2017

**Intention to publish date**

01/12/2017

**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? |
|----------------------------------|----------|--------------|------------|----------------|-----------------|
| <a href="#">Protocol article</a> | protocol | 24/05/2016   |            | Yes            | No              |
| <a href="#">Results article</a>  | results  | 01/01/2019   | 24/01/2019 | Yes            | No              |