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A shared care approach for seriously ill cancer patients between general practice, discharge department and a specialist palliative care team

Submission date 29/10/2007	**Recruitment status** Stopped	☒ Prospectively registered ☐ Protocol
Registration date 05/12/2007	**Overall study status** Stopped	☐ Statistical analysis plan ☐ Results
Last Edited 14/02/2019	**Condition category** Cancer	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00594971

Protocol serial number
N/A

Study information

Scientific Title
A shared care approach for seriously ill cancer patients between general practice, discharge department and a specialist palliative care team

Study objectives
Background:
Approximately one third of all deaths in Denmark are caused by cancer. Both Danish and international research shows that the majority of terminally ill cancer patients wish to die at home. In Denmark only about 25% has this wish fulfilled. The General Practitioner (GP) has traditionally had the full responsibility for the palliative care of terminally ill cancer patients. In recent years changes have been made to the organisation of palliative care: some hospitals have set up specialised palliative care teams and in some areas of Denmark hospices have been established.

Recent research defines a problem when it comes to communication between the hospital and general practice when the patient is being discharged. This is often done in a way that can cause the patient to feel "left in limbo", especially if it is not completely clear to the patient and his or her relatives who has the responsibility for the palliative care.

Objective:
1. To describe consequences for patients, relatives and health care professionals of three different ways of organising palliative care
2. To collect data which describes patients who are candidates to a shared care approach between general practice and a specialised palliative care team
3. To collect data which describes the palliative phase (place of death and palliative care, admissions to hospital, involvement of GP and district nurse etc.)
4. To describe terminally ill cancer patients and their relatives expectations to the health care system

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Central Denmark Region Committee on Biomedical Research Ethics reviewed this trial on the 14th January 2008 and confirmed that this project does not need formal ethics approval as the project is not classified as biomedical research according to the Danish law Regarding Committees (Komiteloven) § 7, no. 1 (ref: 16169).

Study design
The project is based on a clinically controlled randomised trial of two different organisations of palliative care versus usual care.

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied

Terminal cancer/palliative care

Interventions

As of 16/02/2009 the status of this record was changed to 'stopped' due to recruitment problems. The trial officially stopped on the 1st February 2009.

Please note that, as of 30/04/2008, the start and anticipated end dates of this trial were updated from 01/02/2008 and 01/08/2009 to 15/04/2008 and 31/10/2009, respectively.

The intervention is of organisational character. The patients will be randomised into two groups (groups B and C). A group of usual care patients will be included primary to the intervention (group A). The groups are:
A. Usual discharge with regular discharge letter to the GP. The GP, together with the community nurse, is responsible for the palliative care, including referral to a specialist palliative care team, hospice, hospital, etc., if necessary
B. Discharge with referral to a specialist palliative care team. This is a patient-centred shared care model in which the palliative team helps to organise the patient's treatment and care
C. Discharge with extra effort put into improving the communication between the hospital and the GP. The GP will receive a phone call from the doctor who is discharging the patient, a detailed discharge letter, written information about the patient's type of cancer and acute oncological symptoms, name and phone number of the community nurse and name and phone number of a specialist in palliative medicine, who can be contacted for advice. This is a shared care model, where focus is on supporting the health care professionals, and where the patient has as little contact as possible with the palliative team

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Patients wish for place of death and place of terminal care fulfilled: the patient will be asked about preference for place of death and place for terminal care at inclusion and a month later. At the time of death we will be able to establish:
1.1. Where the patient died
1.2. Where the patient spent most of the terminal phase using register based data and information from the GP
2. Relative amount of time spent in hospital in the terminal phase: at the patients time of death we will be able to count number of days spent in hospital using the hospitals electronic patient files
3. A subjective measure of the patients symptoms and quality of life (European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire of Palliative care [EORTC-QLQ-15-PAL]): this will be measured at the time of inclusion and a month later

Key secondary outcome(s))

1. Patient's satisfaction regarding the services of the GP, district nurse and local hospital: will be measured at inclusion and one month later
2. Patient's experiences regarding cooperation and information sharing in the health care system: will be measured at inclusion and one month later
3. Relative's satisfaction regarding the services of the GP, district nurse and local hospital: will be

measured at inclusion, one month later and 2 months after the patients death
4. Relative's experiences regarding cooperation and information sharing in the health care system: will be measured at inclusion, one month later and 2 months after the patients death
5. Relative's experiences regarding the palliative treatment of the patient: will be measured at inclusion, one month later and 2 months after the patients death
6. Subjective burden of relative (Burden Scale for Family Caregivers [BSFC]): will be measured at inclusion and one month later
7. GPs evaluation of the terminal phase: will be measured after the patients death
8. District nurses evaluation of the terminal phase: will be measured after the patients death
9. Hospital doctors evaluation of the terminal phase: will be measured after the patients death

Completion date
01/10/2009

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
Patients, who at the time of inclusion are diagnosed with incurable cancer, i.e. patients who require palliative care. The patients should also:
1. Be 18 years or older
2. Be able to speak and write Danish fluently
3. Give written and spoken consent
4. Be able to manage in their own home, with or without the help of carers and district nurses
5. Be informed about the diagnosis, also that it is incurable
6. Be registered as suffering from a terminal illness or fulfil the criteria for this

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Patients are excluded if they:
1. Have a low level of cognitive skills, which makes it difficult for them to fill in a questionnaire
2. Are residents of a nursing home at the time of inclusion
3. Are receiving oncologic treatment which requires attending an out-patients clinic regularly
4. Already have established contact with a specialist palliative care team at the time of inclusion

Date of first enrolment
15/04/2008

Date of final enrolment
01/10/2009

Locations

Countries of recruitment
Denmark

Study participating centre
Research Unit for General Practice
Aarhus
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8000

Sponsor information

Organisation
University of Aarhus (Denmark) - Research Unit for General Practice

ROR
https://ror.org/01aj84f44

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

Funder Name
Trygfonden (Denmark)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration