Individualised patient education as supportive lung infection protective technique among patients with acute leukaemia

Submission date	Recruitment status No longer recruiting	Prospectively registered	
09/12/2009		☐ Protocol	
Registration date	Overall study status	Statistical analysis plan	
18/05/2010	Completed	[X] Results	
Last Edited	Condition category	Individual participant data	
16/12/2015	Cancer		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Patient education as a complementary non-pharmacological intervention towards hospital acquired lung infection among patients with acute myeloid leukaemia and chemotherapy induced neutropenia

Study objectives

Individualised structured patient education including clinical procedures for self-measurement of Lung Capacity / Spirometry in combination with Positive Expiratory pressure (PEP) can reduce hospital acquired pneumonia.

Ethics approval required

Old ethics approval format

Ethics approval(s)

- 1. The Ethical Scientific Committee of Copenhagen Region, 19/06/2008, ref: H-D-2008-025
- 2. The Danish Data Protection Agency, 22/01/2008, ref: 2008-41-1728

Study design

Randomised controlled clinical intervention study

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Acute Myeloid Leukaemia (AML); lung infection prevention

Interventions

Patient education and training to perform self-measurement of lung capacity and mechanical lung training with Positive Expiratory Pressure (PEP).

Patients are included when diagnosed with AML and chemotherapy has commenced. Follow-up period is planned to 3 months after inclusion.

The intervention is nurse-led and consists of a structured three level based patient education program given individually to each patient. One program given to both control and intervention group is used for patients training in self-measurement of lung capacity / spirometry twice a day with an electronic pocket monitor, 'PiKo-6'. The time spent by the clinical nurse specialist for initial instruction and education in spirometry varies within 1.5 - 2.5 hours per patient.

The second program is provided only to the intervention group and deals with lung training consisting Positive Expiratory Pressure (PEP) using a PEP-flute twice to four times daily depending on values from lung capacity measurement. Time used for initial instruction varies from 30 mins to 1 hour per patient.

Both programs describe focus, actions and aims on each of the three levels in the forms. Patients are left in charge when completing the 3 levels based on appraisal from the clinical nurse specialist. Patients are seen as inpatients or outpatients every 7 - 14 days to discuss patients assessments and visualize their lung capacity on an EDB-based monitor.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

- 1. Incidence of X-ray verified lung infiltrates during the 3 month follow up period
- 2. Forced Expiratory Volume in 1 second (FEV1) as predictive diagnostic tool for pneumonia

Key secondary outcome(s))

- 1. Quality of Life (QOL) EORTC-QLQ-C30
- 2. SF36 short form
- 3. Hospital Anxiety Depression (HAD)
- 4. Self-efficacy
- 5. Coping Mini Mental Adjustment to Cancer (Mini-MAC)

Above outcomes measured at baseline and at 3 month follow up

6. Qualitative findings derived from semi-structured interviews conducted at the end of 3 month follow up.

Completion date

01/12/2010

Eligibility

Key inclusion criteria

Patients (>18 years) with Acute Myeloid Leukaemia (AML) and Myelodysplatic Syndrome demanding intensive intravenous chemotherapy and diagnosed at the Copenhagen University Hospitales Rigshospitalet and Herlev Hospital.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Αll

Key exclusion criteria

- 1. non-Danish speaking
- 2. Psychotic patients
- 3. Patients requiring care in Intensive Care Units (ICUs)

Date of first enrolment

01/10/2008

Date of final enrolment

01/12/2010

Locations

Countries of recruitment

Denmark

Study participating centre

The University Hospitals Centre for Nursing and Care Research UCSF

Copenhagen Denmark 2100

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Sponsor information

Organisation

Lundbeck Foundation (Denmark)

ROR

https://ror.org/03hz8wd80

Funder(s)

Funder type

Charity

Funder Name

Lundbeck Foundation (Denmark) (ref: FP 28/2007)

Alternative Name(s)

Lundbeckfonden, The Lundbeck Foundation

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Denmark

Funder Name

Copenhagen University Hospital Rigshospitalet (Denmark)

Funder Name

Wedell-Wedellsborg Foundation (Denmark) (ref: 381668/933)

Funder Name

ANCOTRANS (Denmark) - Donation

Funder Name

Familien Hede Nielsens Foundation (Denmark)

Funder Name

Ole Wissing's Foundation for Research in Leukaemia (Denmark)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created Date adde	d Peer reviewed	? Patient-facing?
Results article	results	01/03/2016	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/202	.5 No	Yes