

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

Submission date 09/12/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 18/05/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 16/12/2015	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

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 Myelodysplastic 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

All

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

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 added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2016		Yes	No