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

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

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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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 traning 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
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 |