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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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

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 measure
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

Secondary outcome measures
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.

Overall study start date
01/10/2008

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

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)

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Sponsor type
Charity

Website
http://www.ucsf.dk/

ROR
https://ror.org/03hz8wd80

Funder(s)

Funder type
Charity

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

Alternative Name(s)
Lundbeckfonden

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2016		Yes	No