CT Iterative ReConstruction for Low-dose cardiopulmonary Evaluation: diagnosis of pulmonary infections in patients with febrile neutropenia - Circle Study

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To investigate if ultra low-dose chest CT may be a better diagnostic tool than chest X-ray on day 1 of febrile neutropenia. Imaging results will be compared with a consensus diagnosis on the cause of febrile neutropenia made by an expert panel....

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	White blood cell disorders
Study type	Observational invasive

Summary

ID

NL-OMON39846

Source
ToetsingOnline

Brief title
Circle Study

Condition

- White blood cell disorders
- Immunodeficiency syndromes
- Respiratory tract infections

Synonym
Febrile neutropenia, neutropenic fever

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Febrile neutropenia, Mould infection, Pulmonary infection, Ultra low-dose chest CT

Outcome measures

Primary outcome

The main study parameters are chest X-ray, ultra low-dose CT, HRCT and consensus diagnosis. The main endpoint is sensitivity of imaging test for a pulmonary focus of febrile neutropenia as established by consensus diagnosis.

Secondary outcome

Secondary study parameters/endpoints are routinely obtained serum galactomannan test, bronchoalveolar lavage (BAL) and blood tests.

Study description

Background summary

Standard radiological work up for detection of pulmonary infection in febrile neutropenia is done with chest X-ray. But the sensitivity of this test is low, leading to diagnostic insecurity and therefore broad testing of infection possibilities and broad spectrum antibiotic use. We expect that ultra low-dose chest computed tomography (CT) with iterative reconstruction (IR) can detect pulmonary sites of febrile neutropenia 80% more often than routine chest X-ray. Furthermore, we aim to obtain pilot data for the performance of ultra low-dose chest CT on day 5 and week 6 in the detection of pulmonary invasive mould infections compared to the routine-dose high resolution computed tomography (HRCT).

Study objective

To investigate if ultra low-dose chest CT may be a better diagnostic tool than chest X-ray on day 1 of febrile neutropenia. Imaging results will be compared

with a consensus diagnosis on the cause of febrile neutropenia made by an expert panel.
Thereby, a pilot-study to investigate if ultra low-dose chest CT is comparable to HRCT in the characterization of mould infection abnormalities on day 5 and week 6.

Study design

Prospective diagnostic mono-center study.

Study burden and risks

The patient does not have benefit from participating in this study and will receive routine care. For research purposes additional ultra low-dose CT scans are obtained. The additional ultra low-dose CT scans will be analysed after the study has been completed. This study may contribute to a better diagnostic procedure in future patients with febrile neutropenia, limit extensive testing searching for the cause of fever, creates the possibility for more focussed treatment and possibly earlier detection of mould infections. The additional radiation dose on day 1 is 0.25-0.5 mSv (ultra low-dose chest CT) and for the subjects with persistent fever on day 5 and week 6 if applicable 0.25-0.5 mSv (ultra low-dose chest CT), therefore the additional radiation dose is 0.75-1.5 mSv per episode. In comparison, the background radiation in The Netherlands is approximately 2.4 mSv per year. The additional CT visit on day 1 will be combined with the routine chest X-ray and will take the patients an additional 15 - 30 minutes. If a patient has an indication for a routine CT on day 5 and week 6, the additional ultra low-dose image acquisitions will be obtained in the same session as the routine CT and will take an additional minute.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients >= 18 years
- Neutropenia due to chemotherapy given for haematological disease or conditioning regimen for autologous or allogenic stem cell transplantation. Neutropenia is defined as absolute neutrophil count < 0.5 x 109 cells/L or a count of < 1.0 x 109 cells/L with a predicted decrease to < 0.5 x 109 cells/L within 3 days
- Chest X-ray made in the diagnostic work up on day 1 on the radiology department
- Fever (temperature > 38.3°C once or >= 38.0 °C longer than 1 hour) not related to administration of blood products or medication
- Written informed consent

Exclusion criteria

- Patients with a known focus of infection unrelated to the lower respiratory tract
- Patients with a history of probable or proven invasive mould infection without a clinically available normalized chest CT and who use antimycotics
- Previous participation in the study
- Concomitant participation in a study in which the subject is exposed to X-rays
- Chest X-ray made on ward (*bed-thorax*)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-03-2013
Enrollment:	68
Type:	Actual

Ethics review

Approved WMO Date:	13-11-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	13-02-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	27-03-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	15-09-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL41415.041.12