Relation between biomarkers and new radiographic abnormalities in patients hospitalized with Community Acquired Pneumonia

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1. To assess the incidence of pulmonary infiltrates by means of low dose CT-scan in patients with a high clinical suspicion of CAP but with a normal chest x-ray 2. The levels of biomarkers (CRP, PCT, White blood cell count) will be compared to the...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON45017

Source
ToetsingOnline

Brief title
RECAP

Condition

- Hepatobiliary neoplasms malignant and unspecified
- Respiratory tract infections

Synonym
Pneumonia

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Alkmaar
Source(s) of monetary or material Support: Zorggroep longziekten MCA

Intervention

Keyword: Biomarkers, CAP, CT-scan, low-dose CT-scan

Outcome measures

Primary outcome

Presence of infiltrates on low-dose CT-scan.

Secondary outcome

Secondary efficacy analysis as follows:

Mean biomarker levels between groups with a positive CT-scan versus a negative CT-scan. Mean level of biomarker will be assessed by a student T-test if normally distributed or by Mann-Whitney U test if not normally distributed.

The amount of abnormalities on CT-scan will be correlated with the levels of biomarkers by a Spearman or Pearson analysis.

We will try to determine if there*s a relation between duration of symptoms and the chance of a positive CT-scan. This will be done by a binary logistic regression for the outcome yes/no. And by linear regression for duration of symptoms versus the amount of abnormalities on CT-scan.

Study description

Background summary

Pneumonia is possibly under diagnosed in patients presenting to an ER. This due limitations of the chest X-ray. Consequently the true incidence of Community Acquired pneumonia remains unknown. Symptoms and physical findings are

non-specific and infiltrates aren't always visible on the chest X-ray.
Low-dose CT-scans might be useful in distinguishing patients with CAP from those with bronchitis. We believe low-dose CT-scans will prove to be more accurate in diagnosing CAP than the chest X-ray. A pulmonary infiltrate on low-dose CT-scan in combination with elevated biomarkers associated with infection/inflammation might prove the most viable way to diagnose CAP. This combination could also prove useful in distinguishing bacterial from viral infections. Subsequently this might lead to changes in current diagnostic en therapeutic regimes.

Study objective

1. To assess the incidence of pulmonary infiltrates by means of low dose CT-scan in patients with a high clinical suspicion of CAP but with a normal chest x-ray
2. The levels of biomarkers (CRP, PCT, White blood cell count) will be compared to the existence of infiltrates on the low dose CT-scan.
3. The extent of infiltrates will be measured and compared to the level of biomarkers.

Study design

Patients admitted to the emergency ward with a high clinical suspicion of CAP but a clean chest x-ray will be asked to participate. After obtaining informed consent a low dose CT-scan will be performed and compared to biomarkers and findings of the chest x-ray. The study is of an exploratory nature, therefore 44 patients will be asked to participate.

Study burden and risks

Slightly elevated exposure to radiation
It takes about 15 minutes to perform a CT-scan.

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

Male and female patients with a high clinical suspicion of CAP and all criteria listed below:
1. Age 18 or above, no upper age limit will be employed.
2. Clinical presentation of an acute illness with two or more of the following symptoms:
a. Temperature * 38.0 *C (100.4°F)
b. Dyspnoea
c. Cough (with or without expectoration of sputum)
d. Chest pain
e. Rales, rhonchi or wheezing
f. Egophony or bronchial breath sounds
3. No consolidation(s) on the chest radiograph.
4. Written informed consent obtained from the patient or a family member.

Exclusion criteria

Subjects presenting with any of the following will not be included in the study:
1. Severe immunosuppression (HIV infection, chemotherapy).
2. Active neoplastic lung disease.
3. Obstruction pneumonia (e.g. from lung cancer).
4. Pneumonia that developed within 8 days after hospital discharge.
5. Unable and/or unlikely to comprehend and/or follow the protocol.
6. Pregnant and/or lactating women.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2015
Enrollment:	44
Type:	Actual

Ethics review

Approved WMO Date:	27-03-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-10-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-04-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL51063.094.14