Risk Stratification in Elderly Patients in the Emergency Department

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The aim of the study is to identify the risk factors that are associated with an adverse outcome in elderly patients presenting to the ED. Second, we aim to find ways to identify these elderly patients in an early stage (through triage and risk...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON43454

Source
ToetsingOnline

Brief title
RISE UP

Condition

- Other condition

Synonym
n.v.t.

Health condition

alle aandoening waarmee patiënten zich presenteren op de SEH voor de afdeling interne geneeskunde en maag- darm- en leverziekten

Research involving
Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum
Source(s) of monetary or material Support: Ziekenhuis Zuyderland M.C.

Intervention

Keyword: Elderly, Emergency department, Prognosis, Risk-stratification

Outcome measures

Primary outcome

Identification of risk factors associated with an adverse outcome in elderly patients (>=65 years of age) who visit the internist/gastroenterologist at the ED.

* Study parameters:

Patient* characteristics, comorbidity, functional state, cognitive state, demographic parameters, number of previous visits to the hospital in the preceding year, use of medication, vital signs, number of doctor consultations during the stay in the ED, time spent in the ED, number of radiological examinations during ED consultation and diagnosis at admission or discharge from the ED.

*Primary composite endpoint:

- Mortality within 30 days of presentation to the ED

- Readmissions within 30 days after discharge

*Secondary endpoints:

1. Secondary composite endpoint: length of hospital stay (LOS), ICU/MCU admission, mortality within 30 days after presentation to the ED, readmission within 30 days after discharge from the hospital and discharge to another residence than previous address (nursing home/hospice)

2. Length of hospital stay (LOS)

3. ICU/MCU admission

4. Mortality within 30 days after presentation to the ED

5. Readmission within 30 days after discharge from the hospital

6. Discharge to another residence than previous address (nursing home/hospice)

A list of data we will register for all patients who are admitted to the hospital or discharged from the ED can be found in the appendix.

Secondary outcome

1. Discriminating power of triage and risk stratification scores

*Study parameters: MTS, APACHE II, ISAR-HP, abbMEDS, CURB-65, SOFA, GBS

*Endpoints: the above-mentioned primary and secondary endpoints

2. Predictive value of the clinical impression (gut feeling) and disease perception

*Study parameters: questionnaire of clinical impression by the doctor/nurse, disease perception by the patient/companion and the surprise question

*Endpoints: the above-mentioned primary and secondary endpoints

3. Predictive value of laboratory tests

*Study parameters: routine laboratory tests and biomarkers (lactate, hs-TnT,

NT-pro-BNP, PCT and d-dimer)

*Endpoints: the above-mentioned primary and secondary endpoints

Study description

Background summary

Elderly patients (>=65 years of age) constitute an increasing population in emergency departments (EDs) in many countries. These patients are largely different from younger patients and undoubtedly need different approaches in acute care. Compared to younger patients, elderly patients need more time in the ED, use more resources and are frequently misdiagnosed. Furthermore, elderly patients show increased risks of adverse outcomes: hospital admission, readmission after discharge, ED return visits, loss of functional status or death. Commonly used triage systems are not validated in elderly patients. We hypothesize that this factor contributes to a lack of recognition of patients at risk for adverse events or death.

In order to identify elderly patients at risk, we need to learn more about factors associated with adverse outcomes, such as the premorbid state (comorbidity, cognitive and functional state), vital signs, disease severity-/triage scores, clinical first impression, patients* own perception of disease severity and laboratory results.

If we are able to identify high-risk patients in an early stage, treatment can be adjusted, in order improve the outcome and/or well-being of the patient.

Study objective

The aim of the study is to identify the risk factors that are associated with an adverse outcome in elderly patients presenting to the ED. Second, we aim to find ways to identify these elderly patients in an early stage (through triage and risk stratification scores, clinical impression and laboratory results).

Primary objective: To identify risk factors that are associated with an adverse outcome in elderly patients (>=65 years of age) who visit the internist/gastroenterologist at the ED.

Secondary objective:
1. To evaluate the discriminating power of several triage and risk stratification scores in elderly patients who visit the ED.
2. To evaluate the predictive value of the clinical impression (gut feeling) of the doctor/nurse and disease perception by the patient/companion with regard to adverse outcomes in elderly patients who visit the ED.
3. To evaluate the predictive value of laboratory tests (routine tests and biomarkers) with regard to adverse outcomes in elderly patients who visit the ED.

Study design

Multicenter prospective observational cohort study

Study burden and risks

For patients participating in this study, care will be almost completely as usual. As part of this study we want to ask all patients or their family member/companion to fill out a questionnaire. In addition, we want to take two extra venous and one arterial blood sample for patients participating in the study in Zuyderland M.C. Because of lack of financial recourse no extra blood samples will be taken in patients who participate in the study in Maastricht UMC+.

To evaluate disease perception by the patient or their family member/companion, we ask them to fill out a short questionnaire (4 questions) in the ED. We think that this will only be a small burden for the patient and the family member/companion. The day after admission, we will ask the patient a few questions concerning their functional status in order to determine two risk-stratification scores.

Two extra blood samples of 4.5 ml each need to be taken together with routine blood samples in the ED. This blood will be used to determine biomarkers, such as high-sensitivity-troponin, NT-pro-BNP, pro-calcitonin and d-dimer. As the blood will be taken at the same time as the routine venous punctures, no extra risk or burden for the patient is to be expected.

An arterial blood gas sample (1-2 ml) will be taken from the radial artery (or when impossible, the femoral or brachial artery) to determine the acid-base balance and lactate. This blood gas analysis will be used to calculate the APACHE II score. The combination of lactate measurement and the blood gas analysis will provide us with more information on the acid-base balance than lactate alone. Adverse events after arterial puncture could be: possibility of a minor bleeding, which occurs rarely. Therefore, an arterial puncture is expected to be only a minor problem and burden for the patient.

Contacts

Public
Zuyderland Medisch Centrum

Henri Dunantstraat 5
Heerlen 6419 PC
NL
Scientific
Zuyderland Medisch Centrum

Henri Dunantstraat 5
Heerlen 6419 PC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- >=65 years of age
- Presentation to the emergency department (ED) for internal medicine or gastroenterology
- Informed consent

Exclusion criteria

- Earlier participation in study
- No informed consent;Patients who want to participate in the study but refuse an arterial puncture can still participate in the study and are not excluded. We want to include these patients because we can still use other information for the primary objective and remaining secondary objectives.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-07-2016
Enrollment:	600
Type:	Actual

Ethics review

Approved WMO

Date:	18-04-2016
Application type:	First submission
Review commission:	METC Atrium-Orbis-Zuyd

Approved WMO

Date:	06-07-2016
Application type:	Amendment
Review commission:	METC Atrium-Orbis-Zuyd

Approved WMO

Date:	18-07-2016
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

Approved WMO

Date:	14-11-2017
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL55867.096.15