

Sex differences in Emergency Department presentation and risk stratification.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28112

Source

Nationaal Trial Register

Brief title

SEX-ED

Health condition

Acute diseases

Sponsors and support

Primary sponsor: None

Source(s) of monetary or material Support: Leiden University Medical Centre

Intervention

Outcome measures

Primary outcome

in-hospital mortality

Secondary outcome

Study description

Background summary

Background

In many diseases, differences between men and women exist in clinical presentation and outcome, but it is unknown whether these sex differences exist in the Emergency Department (ED) setting. If these sex differences exist in the ED, sex adjusted risk stratification may improve outcomes by better recognition of vital threads.

Aims

1. To assess whether sex differences in the ED exist in clinical presentation (age, presenting complaints, triage category, vital signs, pain scores, laboratory results, number and type of diagnostic tests) and clinical outcomes (disposition (ward, medium care unit (MCU), intensive care unit (ICU)), in-hospital mortality and ED / hospital length of stay (LOS)).
2. To assess whether the association between vital signs, triage category, chief complaints, pain scores and (case-mix adjusted) clinical outcomes are different in men compared to women.

Study design

Observational multi-centre cohort study using the Netherlands Emergency department Evaluation Database (NEED) in which consecutive ED-patients are included.

Data analyses

Descriptive statistics will be used to describe differences between men and women.

Multivariable logistic regression analyses will be used to identify independent determinants of clinical outcomes.

Importance and impact

Insight in sex differences of ED presentation and prognosis may contribute to improved recognition of severely ill patients and sex-adjusted risk stratification.

Study objective

No differences in ED presentation between men and women exist. However, men are at higher risk for mortality.

Study design

We study overall in-hospital mortality or ICU admission from the ED. After discharge we don't follow-up on patients.

Contacts

Public

Leiden Universitair Medisch Centrum
Bart Candel

0644665616

Scientific

Leiden Universitair Medisch Centrum
Bart Candel

0644665616

Eligibility criteria

Inclusion criteria

patients >17 years with an ED visit

Exclusion criteria

Patients <18years, missing gender

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	03-11-2020
Enrollment:	200000
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion	
Date:	03-11-2020
Application type:	First submission

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
NTR-new	NL9030
Other	METC Máxima MC : N20.088

Study results