PLEASE NOTE: *This study has been imported from ClinicalTrials.gov without additional data checks.*

Trial Description

Title

EUROpean Dyspnoea Survey in the EMergency Departments

Trial Acronym

EURODEM

URL of the trial

[---]*

Brief Summary in Lay Language

Braunwald defines dyspnoea as an abnormally uncomfortable awareness of breathing. Breathing discomfort, and its varying degrees of severity, is the one of the most disturbing symptoms patients can experience; and it is one of the main complaints in the patients presenting to the Emergency Department (ED). Dyspnea has a variety of underlying etiologies, like cardiac, pulmonary or metabolic etiologies or a combination of them, since several diseases can cause dyspnea like for instance heart failure (HF), asthma and chronic obstructive pulmonary disease (COPD).

Acute heart failure syndrome (AHFS) is collectively defined as a gradual or rapid change in heart failure (HF) signs and symptoms resulting in a need for urgent therapy. Heart failure (HF) is one of the most important causes of morbidity and mortality in the industrialized world. The prevalence of symptomatic HF is estimated to range from 0.4 to 2.0% in general European population. The incidence increases rapidly with age, and in Europe. Characteristics, clinical presentation, treatment, and outcomes of HF patients admitted to hospital have been adequately described, in Europe and in the United States. The Euro Heart Failure Survey (EHFS) I with 11 327 patients described the demographics of acutely hospitalized HF patients. The ADHERE registry has data on over 100 000 hospitalizations for AHF from the USA. In-hospital mortality was 4 and 7%, in ADHERE and EHFS I, respectively.

This same sensation of breathlessness is what also drives patients with asthma and chronic obstructive pulmonary disease (COPD) to the ED. Chronic obstructive pulmonary disease (COPD) exacerbation accounts for approximately 1.5 million ED visits in the United States per year. It is the third most common cause of hospitalization, with an estimated 726 000 hospitalizations in 2000 in the USA. Previous studies have demonstrated important differences between guideline recommendations and actual management of COPD exacerbation, either in the ED or during hospitalization.

The diagnosis in front of a dyspneic patient in the ED remains a challenge, because of a low sensitivity of the clinical signs associated with the aging of the population and the variety of underlying diseases. Little is known about the Epidemiology of dyspneic patients in the ED at the European level. Diagnosis, prevalence and treatment of the patients may vary among European countries.

Brief Summary in Scientific Language

MAIN OBJECTIVES

- Epidemiologic description of patients presenting to the ED with shortness of breath as main complaint.

- Description of current management in the ED of patients presenting to the ED with shortness of breath as main complaint.

SECONDARY OBJECTIVES

- Sub analysis of ED discharged patients versus admitted patients for characteristics, comparison to recommended care and re-ED visit.

- Determine clinical and/or biological criteria to distinguish between:

- Patients who are treated as outpatients and admitted patients.

- Patients hospitalized in ward and patients admitted to intensive care units (CCU and ICU)

- Prognostic prediction, using clinical and biochemical data

- To determine if ED patients treated for acute heart failure differ from those admitted to hospital.

- Comparison of European data characteristics, investigation, treatment and outcome to similar data in other part of the world.

Organizational Data

- DRKS-ID: **DRKS00005871**
- Date of Registration in DRKS: **2014/09/10**
- Date of Registration in Partner Registry or other Primary Registry: **2014/02/09**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT02060799 (ClinicalTrials.gov)**
- Sponsor-ID: **HLariboisiere (Hopital Lariboisière)**

Health condition or Problem studied

- Free text: **Dyspnea**
- Free text: **Emergencies**
- ICD10: **R06.0 - Dyspnoea**

Interventions/Observational Groups

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **[---]***
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **[---]***
- Purpose: **[---]***

Study Type: **Non-interventional**

Study Type Non-Interventional: **Observational study**

Allocation: **[---]***

Blinding: **[---]***

Who is blinded: **[---]***

Control: **[---]***

Purpose: **[---]***

- Assignment: **[---]***
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- All cause mortality; time frame: 30 days; All cause mortality will be evaluated 30 days after ED visit.

Secondary Outcome

- All cause rehospitalization; time frame: 30 days

Countries of recruitment

- BE **Belgium**
- FI **Finland**
- FR **France**
- DE **Germany**
- IT **Italy**
- NL **Netherlands**
- RO **Romania**
- ES **Spain**
- TR **Turkey**
- UK **United Kingdom**

Locations of Recruitment

- **Country: Germany, Nuremberg**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2014/02/27**
- Target Sample Size: **2500**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- Consecutive patients presenting to the Emergency Department with Dyspnea as main complaint

- 18 years or older

Exclusion criteria

- No acceptance to participate from the patient

Addresses

- **Primary Sponsor**

  Hopital Lariboisière

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***

- **Contact for Scientific Queries**

  Lariboisière Hospital, EuSEM
  Said LARIBI, MD, PhD

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- **Collaborator, Other Address**

European Society for Emergency Medicine

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Sources of Monetary or Material Support

- **[---]***

Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.

- Translation on version: 2

- Last processed date by ClinicalTrials.gov: 2014/11/27

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*