ISRCTN49172439 https://doi.org/10.1186/ISRCTN49172439

CHU-SARI study: Role of respiratory viruses in adult hospitalizations for severe acute respiratory infections (SARI)

Submission date
20/01/2014

Recruitment status
No longer recruiting

Registration date
21/02/2014

Overall study status
Completed

Last Edited
27/02/2014

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Winter hospitalizations for severe acute respiratory infections (SARI) due to an influenza virus have been assessed at University Hospital CHU Mont-Godinne since the 2009 influenza A/H1N1 pandemic wave. All patients presenting to the Emergency Department (ED) are screened according to a SARI case definition. Nasopharyngeal swabs are collected to test for influenza. Recent studies have focused on the role of other respiratory viruses as a cause of illness and death during the winter months. The aims of the study are to assess the impact of influenza and other respiratory viruses during the 2013-2014 winter season, along with the use of internal diagnostic methods in virology.

Who can participate ?
Adult patients matching with the SARI case definition (fever > 38°C or history of fever associated with cough and/or dyspnea (shortness of breath), and requiring hospitalization for more than 24 h), who consent for nasopharyngeal swabbing.

What does the study involve ?
SARI patients will be screened at admission. Nasopharyngeal swabbing is considered as routine practice for SARI patients hospitalized at CHU Mont-Godinne. Infection control measures (transmission-based precautions) are applied as recommended for suspected or documented respiratory viral pathogens. Medical management of patients follows recommendations regarding antiviral treatment for influenza infection, and eventual antibiotic therapy adaptation.

What are the possible benefits and risks of participating ?
The benefits for the patients are the possible initiation of an antiviral treatment for documented influenza infection, and the possible adaptation of antibiotic therapy in case of viral documented infection (influenza and/or another respiratory virus). There are no risks for patients included in the study, as nasopharyngeal swabbing is a non-invasive procedure, and all the medical interventions carried out are same as that performed in standard practice.

Where is the study run from ?
University Hospital Mont-Godinne at Yvoir (Belgium).

When is the study starting and how long is it expected to run for ?
Recruitment started in November 2013 and study will run until April 2014. Participants will be enrolled on the study up to the end of winter period, 2014.

Who is funding the study ?
Mont-Godinne Foundation, Belgium.

Who is the main contact ?
Professor Bénédicte Delaere
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Contact information

Type(s)
Scientific

Contact name
Prof Bénédicte Delaere

Contact details
CHU Mont-Godinne (Catholic University of Louvain)
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5530

Additional identifiers

Study information

Scientific Title
A descriptive observational cohort study to determine the role of respiratory viruses in adult hospitalizations for severe acute respiratory infections (SARI)

Acronym
CHU-SARI

Study objectives
It is hypothesized that winter hospitalizations for acute respiratory infections related to viral pathogens are underestimated. Influenza can lead to severe acute infection, but other respiratory viruses may also contribute to morbidity and mortality, especially in adult patients with risk factors.

Ethics approval required
Old ethics approval format

Ethics approval(s)
CHU Mont-Godinne Ethics Committee, 14/11/2013, ref. BUN 039201318786

Primary study design
Observational

Study design
Descriptive observational cohort study

Study type(s)
Screening

Health condition(s) or problem(s) studied
Infectious diseases/Respiratory viruses/Epidemiology

Interventions
Screening of SARI patients at admission
Nasopharyngeal swabbing
Multiplex rt-PCR for respiratory viruses
Collection and analysis of clinical and epidemiological data

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Patients positive for at least one respiratory virus
2. Patients with risk factors

All outcomes measured by prospective and retrospective review of electronic medical charts of enrolled patients (date of admission as baseline, date of discharge, and date of medical hospitalization report completed).

Key secondary outcome(s)
1. Viral co-infections with two or more respiratory viruses
2. Bacterial co-infections
3. Epidemiology, clinical course and outcome (risk factors, length of stay, complications, intensive care admission, death)
4. Instauration of antiviral treatment following virological diagnosis
5. Adaptation of antibiotic treatment following virological diagnosis

Completion date
15/04/2014

Eligibility

Key inclusion criteria

1. Adult (aged above 16 years)
2. New admission and within 7 days of admission
3. Fever > 38 or history of fever, cough and/or dyspnea
4. Requiring hospitalization for over 24h
5. Oral consent for nasopharyngeal swabbing

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients under 16 years of age
2. Patients already hospitalized and developing a SARI

Date of first enrolment
15/11/2013

Date of final enrolment
15/04/2014

Locations

Countries of recruitment
Belgium

Study participating centre
CHU Mont-Godinne (Catholic University of Louvain)
Yvoir
Belgium
5530

Sponsor information

Organisation
Mont-Godinne Foundation (Belgium)

Funder(s)

Funder type
Charity

Funder Name
Mont-Godinne Foundation (Belgium) (CHU Mont-Godinne, Catholic University of Louvain) (Belgium)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration