INFLUENZA AND ACUTE MYOCARDIAL INFARCTION IN THE COMMUNITY OF MADRID: A RETROSPECTIVE ECOLOGICAL TIME-SERIES STUDY (2013-2018) (FLU-AMI-ECO)

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/36567

EU PAS number

EUPAS36560

Study ID

36567

DARWIN EU® study

No

Study countries

Spain

Study description

Influenza and cold can explain the increased incidence of acute myocardial infarction (AMI) during the winter but, since they are closely related in temperate regions, their relative contribution is not clear. Influenza can be associated to type 1 and type 2 AMI, but few studies have investigated its relationship with ST-elevation AMI (STEMI). The aim of this study is to assess the temporal relationship of flu epidemic with the incidence of STEMI in the region of Madrid (Spain) using the data from the "Código Infarto Registry" from 2013 to 2018. Only STEMI with a demonstrated culprit lesion (type 1 AMI) will be included. The IR of influenza and temperature during five flu epidemic periods (from 40th week through 20th week next year) will be obtained from official records. A time-series analysis will be carried out using quasi-Poisson regression models and distributed lag-nonlinear models, including stratified analyses by sex and age (<65 and >=65 years). The IR of STEMI according to flu vaccination will be explored using data from the STEMI registry and population statistics of vaccination.

Study status

Planned

Research institutions and networks

Institutions

Hospital Universitario Príncipe de Asturias

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Institution

Fundación para la Investigación Biomédica

Contact details

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/07/2020

Study start date

Planned: 31/07/2020

Data analysis start date
Planned: 03/08/2020

Date of final study report
Planned: 30/09/2020

Sources of funding

- Pharmaceutical company and other private sector
- Other

More details on funding

Sanofi Pasteur, S.A., Biomedical Research Foundation, Own resources

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Main study objective:

1. To assess the relationship between the incidence of seasonal influenza and incidence of type I AMI,adjusting for ambient temperature.2. To estimate whether the association between the weekly incidence of seasonal influenza and theweekly incidence rate of type I AMI varies by sex and age3. To explore the impact of flu vaccination on the incidence of type I AMI

Study Design

Non-interventional study design

Ecological

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J07BB) Influenza vaccines

Influenza vaccines

Medical condition to be studied

Acute myocardial infarction

Additional medical condition(s)

Influenza infection

Population studied

Age groups

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

8240

Study design details

Outcomes

Type I Acute Myocardial Infarction (AMI)

Data analysis plan

- The incidence rates (IR) of AMI with ST segment elevation (STEMI) in the population older than 14 years old of the Autonomous Community of Madrid (Spain) will be estimated using the registry "Código Infarto". - The association between the weekly incidence of influenza and the incidence rate (IR) of acute myocardial infarction (AMI) in the ACM will be evaluated using an ecological time-series design. Data will be analysed with quasi-Poisson regression models. The shape of the relationship between the weekly incidence of influenza and the IR of AMI will also be studied distributed lag nonlinear models (DLMN).- The impact of flu vaccine on the incidence of AMI will be explored using the status of flu vaccination and the available population statistics of flu vaccination coverage in the region.

Data management

Data sources

Data sources (types)

Disease registry

Other

Data sources (types), other

Exposure registry

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No