How pregnant women perceive risk related to Congenital Rubella Syndrome: a prospective study conducted at University “Federico II” of Naples

First published: 17/01/2017

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Study Finalised

Administrative details

EU PAS number

EUPAS17302

Study ID

28603

DARWIN EU® study

No

Study countries

☐ Italy

Study description

evaluate the knowledge of congenital rubella infection consequences and theimmunoprophylaxis profile among pregnant women admitted at University Hospital“Federico II” of Naples, in order to make them conscious about the importance of activeprophylaxis to prevent CRS.

Study status

Finalised

Research institutions and networks

Institutions

University of Naples Federico II

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Anna Maria Spera

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/03/2016

Actual: 30/09/2016

Study start date
Planned: 01/03/2016

Actual: 30/09/2016

Date of final study report
Planned: 30/09/2016

Actual: 30/09/2016

Sources of funding

- Pharmaceutical company and other private sector

Study protocol

protocol Spera A et al.pdf (324.58 KB)

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 topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Primary data collection

Main study objective:

evaluate the knowledge of congenital rubella infection consequences and theimmunoprophylaxis profile among pregnant women admitted at University Hospital“Federico II” of Naples, in order to make them conscious about the importance of activeprophylaxis to prevent CRS.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Pregnancy

Population studied

Short description of the study population

Pregnant women admitted at the Emergency Room and/or at the Department of Obstetrics and Gynecology of University “Federico II” of Naples, from March to September 2016.

Age groups

- Adults (18 to < 46 years)

Special population of interest

Pregnant women

Estimated number of subjects

131

Study design details

Outcomes

evaluate the knowledge of congenital rubella infection consequences among pregnant women admitted at University Hospital“Federico II” of Naples, evaluate theimmunoprophylaxis profile among pregnant women admitted at University Hospital“Federico II” of Naples

Data analysis plan

we interviewed all the pregnant women admitted at the Emergency Roomand/or at the Department of Obstetrics and Gynecology of University “Federico II” ofNaples, from March to September 2016, using a multiple choice questionnaire.

Documents

Study results

RESULTS Spera et al.pdf (187.5 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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