

# 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

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### Study ID

28603

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### DARWIN EU® study

No

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### Study countries

☐ Italy

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## Study description

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

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## 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

[annamariaspera@hotmail.it](mailto:annamariaspera@hotmail.it)

### Primary lead investigator

Anna Maria Spera

## Study timelines

### **Date when funding contract was signed**

Planned: 01/03/2016

Actual: 30/09/2016

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### **Study start date**

Planned: 01/03/2016

Actual: 30/09/2016

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### **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

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

Not applicable

## Methodological aspects

### Study type

### Study type list

#### **Study topic:**

Disease /health condition

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#### **Study type:**

Non-interventional study

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#### **Scope of the study:**

Disease epidemiology

#### **Data collection methods:**

Primary data collection

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#### **Main study objective:**

evaluate the knowledge of congenital rubella infection consequences and the immunoprophylaxis profile among pregnant women admitted at University Hospital "Federico II" of Naples, in order to make them conscious about the importance of active prophylaxis 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.

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### **Age groups**

Adults (18 to < 46 years)

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### **Special population of interest**

Pregnant women

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### **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

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## 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)

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## Data management

## Data sources

### Data sources (types)

[Other](#)

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### 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

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### Check completeness

Unknown

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### Check stability

Unknown

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### Check logical consistency

Unknown

## Data characterisation

### Data characterisation conducted

No