# Vitamin A supplementation in children hospitalized for measles in a high-income country

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### Administrative details

#### **EU PAS number**

EUPAS31805

#### **Study ID**

32394

#### DARWIN EU® study

No

#### **Study countries**

Italy

### **Study description**

Worldwide medical authorities recommend vitamin A supplementation for severe measles infection requiring hospitalization. However, evidence supporting its use in high-income countries is lacking. A nationwide vitamin A shortage reported in concomitance with recent measles outbreak in Italy, provided the opportunity to test the efficacy of vitamin A in a high-income setting simulating a random allocation to the treatment.We conducted a prospective controlled cohort study involving children admitted to a tertiarycare hospital in Southern Italy (November 2015 - May 2019). The primary outcome was the duration of fever. Secondary outcomes included the length of hospitalization, the rate of complication, the need of antibiotic treatment and the body temperature.

#### **Study status**

Planned

### Research institutions and networks

### Institutions

### University of Naples Federico II

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### Contact details

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Primary lead investigator

# Study timelines

Date when funding contract was signed

Planned: 01/11/2015

Study start date Planned: 01/11/2015

**Date of final study report** Planned: 31/05/2019

## Sources of funding

• Other

### More details on funding

University

# 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:

Effectiveness study (incl. comparative)

### Main study objective:

Test the efficacy of vitamin A in children hospitalized for measles in a highincome setting.

# Study Design

#### Non-interventional study design

Cohort

# Study drug and medical condition

### Anatomical Therapeutic Chemical (ATC) code

(A11CA01) retinol (vit A) retinol (vit A)

### Medical condition to be studied

Measles

## **Population studied**

#### Age groups

Infants and toddlers (28 days – 23 months) Children (2 to < 12 years) Adolescents (12 to < 18 years)

### Estimated number of subjects

108

## Study design details

#### Outcomes

The duration of fever in patients receiving or not vitamin A, was considered as primary outcomes. The length of hospitalization, the incidence of complications, the need of antibiotic treatment, the highest temperature recorded during infection and side effects attributable to vitamin A were considered as secondary outcomes.

#### Data analysis plan

Vitamin A may reduce the duration of fever by 1.5 days and the length of hospital stay by more than 2 days. Considering those effects as clinically relevant, and assuming an alpha error of 5% with a sampling ratio of 1:2, we initially estimated a study power higher than 80% with the enrollment of 116 children (39 receiving vitamin A supplementation and 77 receiving standard care). However, since May 2019, the number of measles cases significantly dropped in Italy and no other children were hospitalized in the Pediatric Infectious Diseases Unit. We have been able to record data of 36 children receiving vitamin A. Seventy-two children admitted for measles in the same unit and receiving only standard care, due to the vitamin A shortage, were matched for age, gender, season of enrollment (winter season from October 1st to March 31st or summer season from April 1st to September 30th) and presence of underlying chronic conditions, resulting in a study power slightly below 80%.

### Data management

### 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