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

First published: 13/10/2019

Last updated: 19/11/2019

Study Planned

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 tertiary-care 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

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Department of Translational Medical Science – Section of Paediatrics

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Andrea Lo Vecchio

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 high-income 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

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