A Multicenter, Non-interventional, Uncontrolled, Open-label, Observational Study in Children (up to Age 24 Months) to Evaluate Serum Mg Levels Associated with the Intake of Numeta G 16% E (NUMETA G 16% E)

First published: 24/07/2014

Last updated: 31/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS7113

Study ID

23227

DARWIN EU® study

No

Study countries

Belgium

France

Sweden

Study description

This non-interventional, observational study is being undertaken to generate data to assess the impact of Numeta G 16% E on serum magnesium (Mg) levels in full-term, new born infants and children up to 24 months of age who require >70% parenteral nutrition (PN) at study entry and who are expected to require at least 50% PN for 5 days.

Study status

Finalised

Research institutions and networks

Institutions

Baxter Healthcare Corporation

Multiple centres: 11 centres are involved in the study

Contact details

Study institution contact

Baxter Clinical Trials Disclosure Call center Baxter Clinical Trials Disclosure Call center
Global_CORP_ClinicalTrialsDisclosure@baxter.com

Study contact

Global_CORP_ClinicalTrialsDisclosure@baxter.com

Primary lead investigator

Eloise Roussat

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/06/2014

Actual: 30/06/2014

Study start date

Planned: 01/12/2014

Actual: 16/12/2014

Date of interim report, if expected

Planned: 01/02/2016

Actual: 01/02/2016

Date of final study report

Planned: 31/12/2018

Actual: 29/12/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Baxter Healthcare Corporation

Study protocol

Numeta Protocol_03JUL2014_Amendment 1.pdf (232.64 KB)

7032-001-protocol-amend-2-2016aug24.pdf (261.2 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

The primary objective of this study is to generate descriptive data for serum Mg levels in full-term, new born infants and children up to 24 months of age following dosing with Numeta G 16% E.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Non-interventional, observational risk assessment

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(B05BA10) combinations

combinations

Population studied

Short description of the study population

Children (up to Age 24 Months) with the Intake of Numeta G 16% E.

Age groups

- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)

Estimated number of subjects

100

Study design details

Outcomes

Influence of Numeta on the serum Magnesium levels to new born infants and children up to 24 months of age receiving Numeta G16%E, Yes, there are the following secondary endpoints/outcomes as per protocol, however reflected as 'Other Variables' in CSR:-Daily Product Intake (ml/kg/day)-Nutrition Intake (calories by oral, enteral, parenteral)

Data analysis plan

The full analysis set (FAS) will include all subjects who received at least 1 dose of Numeta. All subjects who received 5 days of treatment with Numeta G 16% E and who have a baseline and a postdose serum Mg level will be included in the primary analysis set (PAS).

Documents

Study results

Numaped abstract_21Feb2018_Redacted.pdf (24.66 KB)

Data management

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

Unknown