An Observational Study of SonoVue®/Lumason®-Enhanced Urosonography in Paediatric Subjects with Known or Suspected Vesicoureteral Reflux (VUS for evaluation of Paediatric VUR)

First published: 22/07/2019

Last updated: 14/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS30600

Study ID

47474

DARWIN EU® study

No

Study countries

☐ Italy

Study description

SonoVue has been recently approved in the EU for use in ultrasonography of the excretory tract in paediatric patients from newborn to 18 years to detect vesicoureteral reflux. This is a post-authorization observational, retrospective, comparative, study in paediatric subjects assessed with SonoVue/Lumason-enhanced VUS (VUS group) or VCUG (VCUG group) for evaluation of known or suspected VUR, as part of their standard of care. Subjects will be enrolled at sites performing either VUS or VCUG for evaluation of VUR. Data will be collected for the initial assessment of VUR and patient management decision as well as for the follow-up period of at least 12 months after the baseline VUS/VCUG exam. A documented follow-up at 12 months ± 1 month will be performed after the exam and if not available an intermediate follow up (9, 6, 3 months) will be used.

Study status

Finalised

Contact details

Study institution contact

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Study contact

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Primary lead investigator

MARTIN KRIX

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 07/06/2019

Actual: 07/06/2019

Study start date
Planned: 30/09/2020

Actual: 02/07/2020

Data analysis start date
Planned: 01/08/2021

Actual: 23/09/2021

Date of final study report
Planned: 31/03/2022

Actual: 11/03/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

BRACCO IMAGING SPA

Study protocol

BIM-PTR-AC2955.17-VUR_EMA-B082689-7.0.pdf(893.58 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Other study registration identification numbers and links

BR1-145

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To assess subject management decision and changes during a follow-up period of at least 12-months among children undergoing SonoVue/Lumason-enhanced VUS (VUS group) in comparison with children undergoing VCUG (VCUG group) for assessment of VUR.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Post-authorization observational, retrospective, comparative study

Study drug and medical condition

Name of medicine

SONOVUE

Medical condition to be studied

Vesicoureteric reflux

Population studied

Short description of the study population

The study will be conducted in subjects below 18 years of age who had undergone contrast enhanced VUS with SonoVue/Lumason or VCUG as part of their standard of care at least 12 months prior to enrollment and have a documented follow-up during the 12 months after the baseline exam.

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Estimated number of subjects

400

Study design details

Outcomes

To describe the severity (grading) of VUR and the type of treatment (conservative or surgery) among subjects in the VUS and the VCUG groups with positive findings. To determine the incidence of recurrent UTIs or breakthrough UTIs during the follow-up period among subjects in the VUS and VCUG groups. To estimate the proportion of technically inadequate imaging procedures for both VUS and VCUG

Data analysis plan

In general, summary statistics (mean, median, standard deviation, minimum, and maximum) will be provided for continuous variables, and the number and percentage of each category will be provided for categorical data. Unless

otherwise specified, the analysis will be provided by study group, i.e. VUS and VCUG, and the statistical tests will be 2-sided at 0.05 level of significance. No interim analysis is planned. Missing data will not be imputed in general. Any changes in the original statistical methodology will be documented in the statistical analysis plan. All statistical analyses will be performed using SAS® software.

Documents

Study results

BR1-145 CSR Synopsis.pdf(132.37 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

Retrospective patient data collection, medical records

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