

# 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

### PURI

<https://redirect.ema.europa.eu/resource/47474>

### EU PAS number

EUPAS30600

### Study ID

47474

### DARWIN EU® study

No

## Study countries

☐ Italy

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## 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  $\pm$  1 month will be performed after the exam and if not available an intermediate follow up (9, 6, 3 months) will be used.

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## Study status

Finalised

## Contact details

### Study institution contact

MARTIN KRIX

Study contact

[martin.krix@bracco.com](mailto:martin.krix@bracco.com)

### Primary lead investigator

MARTIN KRIX

## Study timelines

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

Planned: 07/06/2019

Actual: 07/06/2019

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### **Study start date**

Planned: 30/09/2020

Actual: 02/07/2020

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### **Data analysis start date**

Planned: 01/08/2021

Actual: 23/09/2021

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### **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

## Regulatory

**Was the study required by a regulatory body?**

Yes

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**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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**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

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**Non-interventional study design, other**

Post-authorization observational, retrospective, comparative study

## Study drug and medical condition

**Name of medicine**

SONOVUE

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**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.

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### **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)

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### **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

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### **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)

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## Data management

### Data sources

#### Data sources (types)

[Other](#)

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#### 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

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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