A study of pattern of use for gadolinium-based contrast agents (GBCAs) in patients undergoing contrast-enhanced magnetic resonance (CE-MR) examination - a prospective, multicentre, observational study (GBCA Observational study)

First published: 21/11/2017

Last updated: 14/03/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS21473

Study ID

29886

DARWIN EU® study

No

Study countries

France
Germany
Italy
Norway
Poland
Portugal
Spain

Study description

A prospective, multicentre, observational study in patients undergoing CE-MR examination as part of routine clinical practice. Patients will be invited to participate in the study only after the decision has been made by the physician to use contrast agents and Clariscan is already included in the formulary of the hospital/institution as an independent decision prior to investigator taking part in this study. Patients enrolledin the study will not be actively followed up to collect adverse events (AEs) or outcomes. Any spontaneously reported AEs/information will be recorded/reported by the investigators up to 7 days after the magnetic resonance (MR) procedure.

Study status

Ongoing

Research institutions and networks

Institutions

GE Healthcare

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Jakobsen Jarl

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 09/10/2017

Study start date

Planned: 01/02/2018

Actual: 17/12/2018

Data analysis start date

Planned: 01/08/2019

Date of final study report

Planned: 30/09/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GE Healthcare

Study protocol

CLA-17-01 CPR Version 1.0 18Oct2017.pdf (519.61 KB)

1. CLA-17-01 CPR Version 1.5 (clean).pdf (815.65 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

CLA-17-01

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Main study objective:

To understand the pattern of use of GBCAs in magnetic resonance imaging (MRI) centres in Europe.

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(V08CA) Paramagnetic contrast media

Paramagnetic contrast media

Population studied

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)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Special population of interest

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

Estimated number of subjects

5.400

Study design details

Data analysis plan

The pattern of use for GBCAs for MR (MRA/MRI) examination will be summarised for all GBCAs pooled, for non-Clariscan GBCAs pooled, and for all individual GBCAs administered during the study, including Clariscan. The overall pattern of use will be assessed based on summary data from a number of different centre, investigator, and patient-level variables.A qualitative analysis of these variables will be performed describing the overall pattern of use, referral pattern, and challenges in a radiological practice. Additional details are available in the Clinical Trial Protocol.

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.

Composition of steering group and observers

CLA-17-01 Steering Committee composition.pdf (63.86 KB)

Data sources

Data sources (types)

Spontaneous reports of suspected adverse drug reactions

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

Procedures

Procedure of results generation

GCBA_Study_SAP_V1.0_final_fully executed

English (1.02 MB - PDF)

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