Safety and Efficacy of Lipiodol® Ultra Fluid in Association with Surgical Glues during Vascular Embolization

First published: 23/02/2015

Last updated: 02/04/2024

Study Planned

Administrative details

EU PAS number

EUPAS8702

Study ID

8703

DARWIN EU® study

No

Study countries

India

Study description

Non-interventional, transversal with longitudinal follow-up, multicenter, Phase IV (India) study.The study is designed to investigate the safety of Lipiodol® Ultra Fluid in association with surgical glues used in routine medical practice of vascular embolization. In an observational approach, subjects will be enrolled prospectively with the main condition that they are scheduled for at least one session of vascular embolization using Lipiodol® Ultra Fluid in association with surgical glues. Participation to the study will not alter the normal care of the subject. The transversal (i.e. per-procedure) safety evaluation will be enabled by appropriate records of safety events during the time frame of the first session of vascular embolization using Lipiodol® Ultra Fluid in association with surgical. Safety evaluation will be completed with longitudinal records of safety up to 7 days after the first embolization session and with a further per-procedure evaluation including additional sessions of vascular embolization using Lipiodol® Ultra Fluid in association with surgical glues if any during the 7-days follow-up. Efficacy evaluation will rely on the level of lesion(s) obliteration after embolization compared to the pre-procedural target level of obliteration. Exploratory descriptive statistical methods will be used to evaluate safety and efficacy, using both the total population and subsets of patients with similar clinical conditions.

Study status

Planned

Research institutions and networks

Institutions

Dr Suyash Kulkarni,MD

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Suyash Kulkarni

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/03/2015

Study start date

Planned: 15/04/2015

Date of final study report

Planned: 30/06/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Guerbet

Regulatory

Was the study required by a regulatory body?

Yes

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Main study objective:

To evaluate the per-procedure safety of Lipiodol® Ultra Fluid in association with surgical glues during vascular embolization of non-hemorrhagic lesions in routine medical practice.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Non-interventional, transversal with longitudinal follow-up, multicenter

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

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Population studied

Age groups

- 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)

Estimated number of subjects

110

Study design details

Outcomes

Adverse Drugs Reactions, Adverse Events

Data analysis plan

Descriptive statistical methods will be used to report all safety and efficacy assessments in this non-interventional study.For assessment of the primary criterion and secondary criteria related to safety, occurrence of ADRs and AEs will be tabulated in terms of number and percentage as well as their associated characteristics such as intensity, actions taken, outcome, and causal relationship to the study drug. Prevalence of ADRs occurring during the first vascular embolization session will be calculated for the primary criterion.

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

No