Non interventional post-authorisation safety study (PASS) to define the incidence of and potential risk factors for procedure-related neurological adverse events (AE) in patients undergoing ultrasound guided foam sclerotherapy (UGFS) for the treatment of lower limb varicose veins (VV) using Fibrovein 3% and 1% (sodium tetradecyl sulphate, STS, injection) incorporating a drug utilisation study (Fibrovein PASS)

First published: 15/01/2015

Last updated: 02/07/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS8260

Study ID

38779

DARWIN EU® study

No

Study countries

France

United Kingdom

Study description

This is a non-interventional PASS to define the incidence and risk factors for procedure-related neurological AE in patients having Fibrovein ultrasound guided foam sclerotherapy (UGFS) for varicose veins (VV)incorporating a drug utilisation study. The research questions are: 1. What are the incidence, type, severity, duration, treatment (where required), and outcome of procedure-related neurological AE in patients undergoing UGFS for lower limb VV using Fibrovein? 2. To what extent, if any, are these procedure-related neurological AE associated with identifiable patient and treatment characteristics? 3. Post-marketing authorisation (PMA), how is UGFS with Fibrovein being used in the “real world” to treat lower limb VVs (nested drug utilisation study)? The population to be studied comprises adult, non-pregnant, non-breast-feeding, patients undergoing UGFS with Fibrovein for VV. Patient and treatment variables will be collected on Proforma 1. These will include age, gender, BMI, primary versus recurrent, deep venous disease and/or DVT, CEAP grade, type of VV, history of migraine / TIA / stroke / diabetes / high BP, smoking status, known PFO, previous Fibrovein UGFS, unilateral vs. bilateral treatment, method of foam preparation, Fibrovein volume concentration and gas ratio, gas used, number of injections, concomitant treatments, compression regime and duration. Co-investigators will contact the UK Co-ordinating Centre should a SAE occur at the time of treatment or subsequently (details recorded on Proforma 2). Data will be recorded for 10,000 treatments. Non-patient-identifiable data will be entered to a password-protected computerised database. Descriptive

and summary statistics will be used. If the incidence of neurological AE is 0.35%, 10,000 will provide an 80% chance (power) of showing that rate is significantly below 0.5% at the 5% significance level. Patients will be treated according to contemporary “standards of care” at each participating centr

Study status

Finalised

Contact details

Study institution contact

Andrew Bradbury tracy.ellis@heartofengland.nhs.uk

Study contact

tracy.ellis@heartofengland.nhs.uk

Primary lead investigator

Bradbury Andrew

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/10/2014

Actual: 01/10/2014

Study start date

Planned: 01/01/2015

Actual: 06/01/2015

Data analysis start date
Planned: 01/01/2018

Date of interim report, if expected
Planned: 01/01/2016

Actual: 31/01/2016

Date of final study report
Planned: 02/04/2018

Actual: 18/12/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

STD Pharmaceuticals Ltd

Study protocol

Final Fibrovein PASS protocol and appendices 15-01-2015.pdf (431.3 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Data collection methods:

Primary data collection

Main study objective:

1. Define the incidence of procedure-related neurological AE in patients undergoing UGFS for lower limb VV using Fibrovein2. Characterise these AE in terms of type, severity, duration, treatment and clinical outcome3. Describe the relationship, if any, between procedure-related neurological AE and patient and treatment characteristics4. Describe the PMA “real world” use of Fibrovein for UGF

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Post-authorisation safety study

Study drug and medical condition

Medicinal product name, other

Fibrovein

Medical condition to be studied

Varicose vein

Population studied

Short description of the study population

Adult (18 years and over) non-pregnant, non-breast-feeding, patients who are undergoing ultrasound guided foam sclerotherapy (UGFS) with Fibrovein for lower limb varicose veins (VV).

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)

Special population of interest

Other

Special population of interest, other

Varicose vein patients

Estimated number of subjects

10000

Study design details

Outcomes

Procedure-related neurological AE in patients undergoing UGFS for lower limb VV using Fibrovein

---

Data analysis plan

Statistical advice has been sought regarding the sample size required to define, within reasonable CI, the incidence of neurological AE. An event rate of 0.3% equals 30 AE in 10,000 treatments. There is a 50% chance of observing > 30 AE, and a 20% chance of observing > 35 AE. There is, therefore, an 80% chance (power) of observing < 35 AE in association with 10,000 UGFS treatments. If 35 AEs were observed in association with 10,000 UGFS treatments, the 95% confidence intervals would range from 0.24% to 0.49%. This would provide significant (P<0.05) evidence that the rate is less than 0.5%. In other words, if the incidence of procedure-related neurological AE in association with UGFS is 0.35%, a sample size of 10,000 treatment sessions would provide the study with an 80% chance (power) of showing that the rate was significantly below 0.5% at the 5% significance level.

Documents

Study results

Fibrovein PASS final report abstract 20201218.pdf (271.47 KB)

Study report

Fibrovein PASS final report 20201218 signed.pdf (718.67 KB)

Progress report December 2015.pdf (266.42 KB)

Study, other information

Progress report December 2015.pdf (266.42 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

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