CONTOUR: Condition of Submental Fullness and Treatment Outcomes Registry (A Registry of Submental Fullness, Treatment Options Administered, and Associated Outcomes)

First published: 09/11/2016

Last updated: 14/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS16159

Study ID

22717

DARWIN EU® study

No

Study countries

- ☐ Canada
- ☐ United States

Study description

Objective The primary objective of this registry is to develop a comprehensive understanding of the condition of submental (SM) fullness due to submental fat (SMF), how it is treated in current clinical practice, and the risks and benefits associated with its treatment Study Design This is a prospective, observational, multi-center registry. Enrolled patients will provide information related to the condition and treatments of interest and will permit their physicians to provide any available data concerning their condition status and treatment Treatment Procedures The eligibility of patients for treatment, and the treatment administered, will be determined by the physician Patient Population Adult male and female patients, aged 18 years and above, presenting with SM fullness due to the accumulation of unwanted SMF, and considered by their treating physician to be a candidate to receive treatment of SM fullness by reduction of SMF Sample Size Approximately 1000 patients will be recruited from approximately 100 sites in the US and Canada Study Procedures Eligible patients will be enrolled in the registry and data will be collected from patients who elect treatment until their SMF reduction treatment is completed or discontinued. At enrollment, data on previous relevant SMF and facial aesthetic treatment(s) will be collected from the patients, and as necessary, their medical records, along with baseline SMF assessments and information on treatment goals Duration Data collection is anticipated to continue for approximately 15 months Data Collection EDC will be used to collect study related data. Data on Baseline information, treated related events, adverse events during follow-up and treatment outcomes will be collected Analysis Analyses will be based upon all patients who were enrolled and have at least one post-baseline visit. Data will be summarized, by type of SMF reduction treatment, with descriptive statistics, and presented in listings

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Study status

Finalised

Research institutions and networks

Institutions

Parexel International

United States

First published: 19/10/2010

Last updated: 10/12/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

Anita Verga CT.Disclosures@abbvie.com

Study contact

CT.Disclosures@abbvie.com

Primary lead investigator

Anita Verga

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 20/10/2014

Actual: 30/12/2014

Study start date
Planned: 12/05/2015

Actual: 12/05/2015

Date of final study report
Planned: 30/06/2016

Actual: 26/10/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Allergan

Study protocol

(US & Candada) Kythera Registry Protocol.pdf (296.13 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Other study registration identification numbers and links

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The primary objective of this registry is to develop a comprehensive understanding of the condition of submental (SM) fullness due to submental fat (SMF), how it is treated in current clinical practice, and the risks and benefits associated with its treatment.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Belkyra

Population studied

Short description of the study population

Adult male and female patients, aged 18 years and above, presenting with submental (SM) fullness due to the accumulation of unwanted submental fat (SMF), and considered by their treating physician to be a candidate to receive treatment of SM fullness by reduction of SMF.

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

1000

Study design details

Data analysis plan

Results for SMF assessments will be summarized with descriptive statistics at each time point. Changes from baseline will be summarized descriptively for each treatment cohort at each post-baseline assessment. Exploratory analysis of covariance (ANCOVA) methods will also be used to assess change from baseline at the end-of-treatment follow-up time point, where treatment type and baseline score will be included in the model. AE and AE mitigation data will be summarized with descriptive statistics, by type of SMF reduction treatment, system organ class (SOC), and preferred term (PT), and presented in listings. The duration (days) and severity of pain, swelling, and bruising will be summarized by type of SMF reduction treatment, by treatment session, and overall. Pain scores from the Pain Numeric Rating Scale will be summarized with descriptive statistics by type of SMF reduction treatment and time point.

Documents

Study results

CSR Allergan_220889_Abbreviated Study Report Amendment_26October2017_Abstract_Redacted.pdf (689.11 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