CONTOUR Australia: Condition of Submental Fullness and Treatment

First published: 11/01/2018

Last updated: 14/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS22012

Study ID

36552

DARWIN EU® study

No

Study countries

Australia

Study description

The primary objective of this registry is to develop a comprehensive understanding of how Belkyra is utilized in clinical practice in Australia, following its approval for the treatment of submental fullness due to submental

fat, in order to further inform assessment of the risks and benefits associated with its treatment.

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

Multiple centres: 6 centres are involved in the study

Contact details

Study institution contact

Suzanne St Rose CT.Disclosures@abbvie.com

Study contact

CT.Disclosures@abbvie.com

Primary lead investigator

Suzanne St Rose

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 16/10/2017

Actual: 16/10/2017

Study start date

Planned: 01/03/2018

Actual: 20/03/2018

Date of final study report

Planned: 29/05/2020

Actual: 12/03/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Allergan

Study protocol

Belkyra AU Protocol_CMO-AP-FAS-0505_Version 1.1_27Sept2017_Amendment 1_C.._ (005).pdf (178.46 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

CMO-AP-FAS-0505

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Safety 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 how Belkyra is utilized in clinical practice in Australia, following its approval for the treatment of submental fullness due to submental fat,

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Phase 4, prospective, observational, multi-center registry

Study drug and medical condition

Medicinal product name, other

Belkyra

Population studied

Short description of the study population

Patients considering treatment to reduce submental fat (SMF) and who plan to pursue treatment with Belkyra™ will be recruited. Eligible patients will be enrolled in the registry, and patients who elect treatment with Belkyra™ will be followed until their SMF reduction treatment is completed or discontinued.

Patients must have met all of the following criteria for inclusion in the study:

Inclusion Criteria:

1.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 SMF reduction treatment with Belkyra™.

2.Patient had confirmed plans with their treating physician to receive treatment with Belkyra™.

3.Signed informed consent by the patient, obtained before any study-related activities were undertaken.

4.Willing to complete all patient assessment questionnaires.

5.Signed release form by the patient, permitting abstraction of the patient’s medical records at baseline and during participation in the registry.

Exclusion Criteria:

1.Severe skin laxity, defined as superficial wrinkling, loose skin separated from deeper neck structures, and/or marked skin redundancy (draping and/or sagging), per the physician’s judgment.

2.Any other cause of fullness in the SM area (e.g., thyroid enlargement, thyromegaly, cervical adenopathy, cervical lymphadenopathy, pronounced submandibular glands, lymph nodes, and muscles) other than localized SMF.

3.Participating in an interventional clinical study, currently or within 30 days before enrolment.

4.Participated previously in an interventional clinical study involving Belkyra™

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

100

Study design details

Data analysis plan

Data will be summarized with descriptive statistics, and presented in listings. Demographic and baseline characteristics will be summarized. Post-baseline values and change from baseline in selected outcome variables will be summarized with descriptive statistics, and, where appropriate, graphical presentations, and presented in listings. All statistical tests will be tested on two-sided significance level of 0.05 and will be considered exploratory.

Documents

Study results

CMO-AP-FAS-0505 CSR Synopsis 12 Mar 2020.pdf (161.12 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