Evaluation of the Safety and Effectiveness of BELKYRA® Inj. for the Treatment of Patients with Submental Fullness due to Submental Fat: A Postmarketing Surveillance Study in Korea

First published: 30/08/2018

Last updated: 14/03/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS23762

Study ID

25581

DARWIN EU® study

No

Study countries

☐ Korea, Republic of

Study description

This study is a prospective, observational postmarketing surveillance (PMS) conducted under the requirements of the Korean Ministry of Food and Drug Safety (MFDS) to evaluate the safety and effectiveness of BELKYRA Inj. in routine clinical settings when administered to patients in Korea for the improvement of moderate to severe convexity or fullness associated with SMF in adults.

Study status

Ongoing

Research institutions and networks

Institutions

DreamCIS

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Suzanne St Rose

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/04/2018

Actual: 15/12/2017

Study start date

Planned: 30/09/2018

Actual: 07/09/2018

Data analysis start date

Planned: 31/03/2023

Date of final study report

Planned: 30/11/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Allergan

Study protocol

CMO-EPI-FAS-0537_FINAL_V1.0_20170929_ENG_clean_ Redacted.pdf(886.25 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-EPI-FAS-0537

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Main study objective:

1. To assess the safety profile of BELKYRA routine Inj. in routine clinical practice in adult patients treated for SM fullness due to SMF2. To assess the effectiveness of BELKYRA Inj. in routine clinical practice in adult patients treated for SM fullness due to SMF.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

Belkyra

Medical condition to be studied

Fat tissue increased

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

600

Study design details

Outcomes

All adverse events that occur during and/or after administration of BELKYRA injection treatment throughout the follow-up period, Investigators' and patients' rating of improvement of fullness associated with submental fat, during follow-up using validated scales.

Data analysis plan

Full analysis set - patients whose case report form were retrieved: the demographic data, baseline characteristics including diagnosis, treatment history, concurrent disease, etc. and concomitant medications • Safety analysis set– patients who received an initial BELKYRA Inj. treatment, completed the Follow-up/Exit Visits (non-treatment) within 3 months of the last BELKYRA Inj. treatment for safety information (via in-office visit or telephone) with case report forms retrieved• Effectiveness analysis– patients who received an initial BELKYRA Inj. treatment and have been evaluated for effectiveness of BELKYRA Inj. for the treatment of excess SMF by the investigator or by the patient.

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 source(s), other

Medical Clinical Data Korea, Republic of

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