A Retrospective Chart Review Study to Evaluate Safety of McGhan Single Lumen Gel-Filled Breast Implants in Patients in China

First published: 16/01/2020

Last updated: 14/03/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS32613

Study ID

35133

DARWIN EU® study

No

Study countries

☐ China

Study description

This study is a retrospective chart review and entails review of medical records of patients enrolled in about 5 hospitals/clinics in China, and who have undergone breast augmentation or reconstruction with McGhan breast implants between 24 December 2015 and 31 December 2019. The safety of McGhan breast implants (textured and smooth) will be evaluated based on occurrence of local complications including capsular contracture, malposition of implant, seroma/late seroma and anaplastic large cell lymphoma (ALCL).

Study status

Ongoing

Research institutions and networks

Institutions

Syneos Health

United Kingdom

First published: 23/04/2015

Last updated: 06/03/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Luan Jie

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 20/11/2019

Study start date

Planned: 01/04/2020

Actual: 01/04/2020

Date of final study report

Planned: 30/10/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Allergan

Study protocol

China McGhan Breast Implant PASS Protocol_Final_V1.0_20Nov2019_Redacted.pdf (490.13 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Other study registration identification numbers and links

MED-EPI-PLS-0637

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Main study objective:

Evaluate the safety profile of McGhan breast implants in patients who have undergone breast augmentation or reconstruction surgery between 24 December 2015 and 31 December 2019 in different centers in China

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Open-label, retrospective chart review

Study drug and medical condition

Medical condition to be studied

Breast enlargement

Breast reconstruction

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

400

Study design details

Data analysis plan

Patient demographics, relevant medical history, indication for surgery, implant device characteristics, procedure-specific details, pre- and post-operative

treatments, and any additional procedures at or around time of surgery will be summarised using descriptive statistics. The safety analysis will be performed on patients for whom an SAE or AE of Special Interest was recorded. The number and percentage of patients reporting SAEs and AEs of special interest will be presented by system organ class and preferred term.

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

Retrospective chart review

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