A Post-Market Clinical Follow-up of EARFOLD® Implantable Clip System in general surgical practice

First published: 25/10/2016

Last updated: 31/03/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/22546

EU PAS number

EUPAS15927

Study ID

22546

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

Study is a multicentre, observational study of patients who receive at least one EARFOLD® implant. The overall objective of the study is to assess adverse events (AEs) associated with EARFOLD® implants in usual surgical practice when used for correction of prominent ears. Primary Objective: Characterise and assess the incidence rates of • Infections • Re-operations • Erosions Secondary Objectives: 1) Assess the incidence rates of other AEs in patients who receive at least one EARFOLD® implant. 2) Compare the incidence of AEs of EARFOLD® implants with those of standard otoplasty. 3) Aesthetic outcome of surgery as assessed by patient satisfaction. Study Population Inclusion criteria The population will consist of all patients who have received at least one EARFOLD® implant at the trained sites in the United Kingdom. Exclusion criteria: Patients known to have impaired healing (e.g. but not restricted to, Ehlers-Danlos Syndrome or Scleroderma). Patients with body dysmorphic disorder. Patients with an active infection of the ear or at any other body site. Data Sources A CRF will be completed by the physician for all subjects at the consult visit, at the time of surgery, and 3 months post-operation. The subject will complete a Patient Evaluation Measure (PEM) at the 3 month post-operation visit to assess satisfaction with the outcome of the procedure and psychosocial well-being. Sample Size At least 30 patients who receive an EARFOLD® will be enrolled Data Analysis This study will provide a descriptive analysis only. AEs will be presented by site for each AE. AEs will also be presented cumulatively. The proportion of infections, re-operations, erosions and other complications of interest will be calculated. The data will be compared to a summary of AEs associated with conventional otoplasty obtained from a systematic review of the literature. Aesthetic outcome data will be presented based upon the completed PEM forms.

Study status

Finalised

Research institutions and networks

Institutions

Royal Free Hospital

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Verga Anita

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/06/2016

Actual: 15/06/2016

Study start date

Planned: 31/12/2015

Actual: 28/06/2016

Date of final study report

Planned: 18/03/2017

Actual: 22/03/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Allergan

Study protocol

20160516 EarFold PMCF Protocol Final v2.pdf(123.88 KB)

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Medical device

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Main study objective:

Characterise and assess the incidence rates of • Infections • Re-operations • Erosions in patients who receive at least one EARFOLD® implant.

Study Design

Non-interventional study design

Cohort

Population studied

Short description of the study population

Patients who receive at least one EARFOLD® implant.

Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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

30

Study design details

Outcomes

Infection Rates Re-operation Rates Erosion Rates, Other AEs

Data analysis plan

Descriptive data analysis only. The proportion of infections, re-operations, erosions and other complications of interest will be calculated. The data will be compared to a summary of AEs associated with conventional otoplasty obtained from a systematic review of the literature.

Documents

Study results

Post-Market Surveillance report - Final 28Feb2017 UBC.pdf(111.11 KB)

Data management

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

Unknown