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

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## Administrative details

**Study description** 

EU PAS number		
EUPAS15927		
Study ID		
22546		
DARWIN EU® study		
No		
Study countries		
United Kingdom		

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

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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

## **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**

Unknown