Safety evaluation of mid-urethral slings (SOFT)

First published: 24/03/2022

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Study Ongoing

Administrative details

EU PAS number

EUPAS44570

Study ID

44571

DARWIN EU® study

No

Study countries

☐ France

Study description

In the field of urology, an emblematic example of the need for post-marketing evaluation of implantable devices is that of sub-urethral slings (SUBs), implanted to treat female urinary incontinence. These devices present a risk of

infection, erosion or urinary obstruction that may lead to further surgery. They also present a risk of chronic pain. It is against this backdrop that in 2019 in the UK, BSUs were removed from NICE's management guidelines for stress urinary incontinence in women. The main aim of this study is to estimate the incidence of surgical re-interventions after suburethral sling placement, in the short (up to one year of follow-up), medium (between 1 and 5 years of follow-up) and long (5 years of follow-up)term.

Study status

Ongoing

Research institutions and networks

Institutions

Assistance Publique - Hôpitaux de Paris (AP-HP)

France

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Institution **Hospital/Clinic/Other health care facility**

Contact details

Study institution contact

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Primary lead investigator

Cyrille GUILLOT-TANTAY

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/01/2021

Actual: 23/06/2021

Study start date

Planned: 01/01/2021

Actual: 07/07/2021

Data analysis start date

Planned: 01/04/2022

Date of final study report

Planned: 30/06/2023

Sources of funding

- Other

More details on funding

French Ministry of Health

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Main study objective:

The main aim of this study is to estimate the incidence of re-interventions after suburethral sling implantation in the short (up to one year of follow-up), medium (between 1 and 5 years of follow-up) and long term (5 years of follow-up).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Stress urinary incontinence

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

330000

Study design details

Outcomes

The primary endpoint is the occurrence of a urological re-intervention identified by the CCAM codes for re-interventions, corresponding to removal or section of the sling. -Patients’ characteristics -Diagnosis of urinary incontinence leading to a sling procedure -Severe (i.e. leading to hospitalization) complications linked to the implantation of slings -Severe and non-severe complications linked to the modifications of the urinary system due to the sling -Reoperation for urinary

incontinence -Global direct and indirect costs -Risk factors of complication

Data analysis plan

Women will be followed from the index date (date of implantation) until the first of the following events: exit of the health insurance scheme, death or end of the study 2019 December 31st (and for each objective, the date of the outcome of interest). Incidence of surgical re-intervention and incidence of other related complications will be estimated using Kaplan Meier method. Related rates will be reported at different times of interest. Concerning the risk of non specific complications, the analysis will compare the rate of complications occurring in exposed women with that occurring in unexposed women, each woman who had a mid-urethral sling implantation will be matched with 1 woman who did not have one at the index date (dynamic matching). Matched unexposed women who received a sling during follow-up will be censored at that date in the unexposed group and will start their contribution to the exposed group (time-related exposure). Matching will be done on a propensity score.

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

"Système National des Données de Santé, SNDS France"

Data sources (types)

Administrative healthcare records (e.g., claims)

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