

EVADEF - Medico-Economic Evaluation of Automatic Implantable Defibrillator

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General

Identification

Detailed name Medico-Economic Evaluation of Automatic Implantable Defibrillator

Sign or acronym EVADEF

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation

CNIL

General Aspects

Medical area Cardiology

Keywords psychological impact, Complications, death

Scientific investigator(s) (Contact)

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Collaborations

Funding

Funding status Public

Details Ministère de la Santé (Soutien aux innovations diagnostiques et thérapeutiques coûteuses - STIC).

Governance of the database

Sponsor(s) or organisation(s) responsible Société Française de Cardiologie

Organisation status Private

Additional contact

Main features

Type of database

Type of database Study databases

Study databases (details) Longitudinal study (except cohorts)

Database recruitment is carried out by an intermediary A selection of health institutions and services

Database recruitment is carried out as part of an interventional study No

Additional information regarding sample selection. Prospective. Inclusion cut-off date: 01/06/2005.

Database objective

Main objective To assess the cost of automatic implantable defibrillator usage in France. Secondary objective: - Complications associated with automatic implantable defibrillators; - To investigate cause-specific mortality in patients with automatic implantable defibrillators; - The psychological impact of automatic implantable defibrillators; - Incidence of appropriate and inappropriate therapies.

Inclusion criteria All patients who received an automatic implantable defibrillator

Population type

| | |
|-----|---|
| Age | Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years) Great age (80 years and more) |
|-----|---|

| | |
|--------------------|-----------------|
| Population covered | Sick population |
|--------------------|-----------------|

| | |
|--------|---------------|
| Gender | Male Woman |
|--------|---------------|

| | |
|----------------|----------|
| Geography area | National |
|----------------|----------|

| | |
|------------------------------|------------------------------|
| Detail of the geography area | 22 centres throughout France |
|------------------------------|------------------------------|

Data collection

Dates

| | |
|--|---------|
| Date of first collection (YYYY or MM/YYYY) | 06/2003 |
|--|---------|

| | |
|---|------|
| Date of last collection (YYYY or MM/YYYY) | 2005 |
|---|------|

Size of the database

| | |
|--|---------------------------|
| Size of the database (number of individuals) | [1000-10 000[individuals |
|--|---------------------------|

| | |
|--------------------------------------|------|
| Details of the number of individuals | 2418 |
|--------------------------------------|------|

Data

| | |
|-------------------|---------------------------|
| Database activity | Data collection completed |
|-------------------|---------------------------|

| | |
|------------------------|------------------|
| Type of data collected | Declarative data |
|------------------------|------------------|

| | |
|---------------------------|--|
| Declarative data (detail) | Paper self-questionnaire Face to face interview |
|---------------------------|--|

| | |
|-----------------------|----|
| Presence of a biobank | No |
|-----------------------|----|

| | |
|---------------------------|--|
| Health parameters studied | Health event/morbidity Health event/mortality |
|---------------------------|--|

Procedures

| | |
|------------------------|---|
| Data collection method | - Self-administered questionnaire: manual input |
|------------------------|---|

from a paper questionnaire. - Interviews: input from a paper questionnaire. - Clinical examinations: handwritten. - Biological analysis: handwritten.

| | |
|---------------------------------------|---------------|
| Participant monitoring | Yes |
| Details on monitoring of participants | Every 2 years |
| Links to administrative sources | No |

Promotion and access

Promotion

Link to the document <http://tinyurl.com/Hal-EVADEF>

Description List of publications in HAL

Link to the document [http://www.ncbi.nlm.nih.gov/pubmed/?term=%28Marijon+E\[author\]+OR+Le+Heuzey+JY\[author\]%29+AND+evadef](http://www.ncbi.nlm.nih.gov/pubmed/?term=%28Marijon+E[author]+OR+Le+Heuzey+JY[author]%29+AND+evadef)

Description List of publications in Pubmed

Access

Terms of data access (charter for data provision, format of data, availability delay) Data may not be used by academic teams

Access to aggregated data Access on specific project only

Access to individual data No access