# Surveillance of adverse events associated with totally implanted venous-access ports

Submission date	Recruitment status	Prospectively registered
26/06/2010	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
13/01/2011	Completed	Results
Last Edited	Condition category	Individual participant data
13/01/2011	Cancer	<ul><li>Record updated in last year</li></ul>

### Plain English summary of protocol

Not provided at time of registration

# Contact information

### Type(s)

Scientific

### Contact name

Dr Véronique Merle

### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

2009/081/HP

# Study information

### Scientific Title

Impact of implementing a surveillance of adverse events associated with totally implanted venous-access ports in cancer inpatients: a quasi-experimental study

### Acronym

SCHIC (Surveillance des Chambres Implantables en Continu)

### **Study objectives**

Implementing a surveillance of adverse events associated with totally implanted venous-access ports in cancer inpatients could identify suboptimal process of care and lead to the implementation of corrective actions and, in time, to a decrease in the occurrence of adverse events, improvement in quality of care, and improvement in work-related quality of life of health care workers.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

French regulation does not require ethics approval for such trials as ours without direct intervention performed on patients. However, the approval of the Local Ethics Committee was sought and received on 25th May 2010.

### Study design

Quasi-experimental interventional uncontrolled trial

### Primary study design

Interventional

### Secondary study design

Non randomised controlled trial

### Study setting(s)

Other

# Study type(s)

Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied

Cancer

#### Interventions

The trial does not compare treatments. The intervention is the implementation of a surveillance scheme associated with morbidity-mortality conferences. The aim is to assess the impact of this implementation on quality of care, and on work-related quality of life for health care workers.

### Intervention Type

### Other

### Phase

Not Applicable

### Primary outcome measure

- 1. Adverse events frequency
- 2. Number of corrective actions identified and implemented
- 3. Assessment of health care workers perception of the surveillance and MMC scheme

Measured after a 12 month period of surveillance and 4 morbidity-mortality conferences (1 every 3 months).

### Secondary outcome measures

- 1. Assessment of the repercussion of adverse events associated with totally implanted port by interview with patients
- 2. Description of objective consequences of adverse events (prolongation of stay, diagnostic or therapeutic procedures, port replacement, delay in the administration of chemotherapy)
- 3. Assessement of sensibility and specificity of adverse event identification by the surveillance

Measured after a 12 month period of surveillance and 4 morbidity-mortality conferences (1 every 3 months).

### Overall study start date

01/11/2009

### Completion date

01/11/2011

# **Eligibility**

### Key inclusion criteria

Two hospitals will participate in the study: a university hospital, and a hospital exclusively dedicated to the care of cancer patients. In each hospital, wards performing cancer intravenous chemotherapy as a usual activity will be approached and proposed the implementation of a surveillance of adverse events associated with totally implanted venous-access ports. Only patients (male or female adults above 18 years old) with totally implanted venous-access ports used for cancer chemotherapy will be included in this surveillance.

## Participant type(s)

Patient

### Age group

Adult

### Lower age limit

18 Years

### Sex

Both

### Target number of participants

1000 patients are expected to included in the surveillance for each 3-month period

### Key exclusion criteria

Wards with no, or infrequent, activity of cancer chemotherapy will not be included in the study. In wards participating in the study, patients with totally implanted venous-access ports used for other treatment than cancer chemotherapy (antibiotics, parenteral nutrition, etc.) will not be included in the surveillance.

### Date of first enrolment

01/11/2009

### Date of final enrolment

01/11/2011

# Locations

### Countries of recruitment

France

# Study participating centre

Department of Epidemiology and Public Health

Rouen France

76031

# Sponsor information

### Organisation

French Ministry of Health and Sport (France)

### Sponsor details

14, avenue Duquesne Paris France 75350 +33 (0)1 40 56 56 09 patrick.gardeur@sante.gouv.fr

### Sponsor type

Government

### Website

http://www.sante-sports.gouv.fr/

# Funder(s)

## Funder type

Government

### **Funder Name**

French Ministry of Health (France) - Research Program on Quality in Hospital Care

# **Results and Publications**

# Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration