ISRCTN57640029 https://doi.org/10.1186/ISRCTN57640029

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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
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Sponsor information

Organisation
French Ministry of Health and Sport (France)

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Sponsor type
Government

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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