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Totally Implantable Access Ports

Submission date 20/03/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 31/03/2009	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 31/03/2009	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

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
IEO S16/199

Study information

Scientific Title

Percutaneus subclavian versus internal jugular versus cephalic surgical venous cut-down for central venous access of totally implantable ports for long-term chemotherapy: a prospective randomised trial

Acronym
TIAP

Study objectives
The purpose of this prospective randomised trial is to compare a percutaneous approach to SVC (subclavian or internal jugular vein) with a surgical cut-down access to the cephalic vein, with respect to complication rates (early and late), global costs (including the costs for diagnosis and appropriate treatment of observed complications), and patients' compliance and satisfaction, to clarify whether or not there is any inherent superiority of one approach over another for this clinical indication.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the European Institute of Oncology gave approval on the 25th February 1999 (ref: IEO S16/199)

Study design
Randomised interventional open single centre phase III three armed study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Solid tumours

Interventions
1. Percutaneous subclavian
2. Internal jugular
3. Cephalic surgical venous cut down

Ports and routes of access to central veins:
Patients were randomly assigned to undergo implantation of a single type of port, constructed of titanium and silicone rubber, with a attached 6-F polyurethane catheter tubing (Bard Port,

Bard Inc., Salt Lake City, UT), through a percutaneous landmark access to internal jugular vein, a 2D-US-guided infraclavicular access to subclavian vein or a surgical cut-down access through the cephalic vein at deltoidpectoralis groove. Generator of the assignment was separated from the executor; randomisation was intra-operatively carried out by the data manager of the trial using a computer-assisted procedure and communicated to the operators. Devices were implanted under local anaesthesia in an operating room or in an angiographic suite, using maximal sterile barrier precautions. A confirmatory chest X-ray was always obtained after the placement. Data from the implantation and follow-up of these patients were entered into a software registry and analysed by epidemiologists-biostatisticians.

A follow-up continued on an outpatient basis at regular intervals of 15 - 21 days until the device was removed, the patient died or the study was closed (30th June 2007). The planned minimum follow-up period was 6 months for each patient. Power and color Doppler ultrasonography of internal jugular and subclavian veins was carried out at regular intervals (1 and 4 months after implant) or anytime when clinically suggested by the appearance of arm or facial swelling and/or pain. Patients with positive or dubious ultrasound (US) scans underwent a neck-chest computerised tomography scan, with i.v. contrast medium administration. Implanted ports have been flushed with 20 ml of normal saline and then filled with sterile heparinised saline after each infusion of medication or blood withdrawal (5 ml of a solution containing 50 IU/ml). If the port remained unused for long periods of time, the heparin lock was changed once every 28 days. Complications were recorded according to the timing of occurrence: early (intra-operative and post-implantation period to first use) and late complications (occurring after the first chemotherapy course given through the device). Patients who died within 6 months were retained in the analysis and were recorded as having no late complications unless one was noted before death.

Intervention Type
Other

Phase
Phase III

Primary outcome measure
To evaluate early and late complications related to implant and use of the devices, related to different approaches and measured as:
1. Prevalence of peri-operative complications (pneumothorax, clinically relevant bleeding)
2. Prevalence of port-related bacteraemia, cutaneous site and pocket infections
3. Prevalence of malfunction of the device (obstruction of the line, dislocation of the catheter, etc.)
4. Prevalence of catheter break and embolisation
5. Prevalence of clinically evident and silent venous thrombosis

Secondary outcome measures
1. Costs for implant
2. Management of the devices and related complications
3. Evaluate the patients' compliance and satisfaction for the adopted procedure
4. Evaluate the quality of life of the patients

Overall study start date
01/07/2003

Completion date
31/12/2006

Eligibility

Key inclusion criteria
1. Patients (aged 18 - 75 years, either sex) bearing solid tumours who are candidate to chemotherapy treatment for at least 4 months
2. Informed signed consent
3. Performance status 0 - 2 (according to Eastern Cooperative Oncology Group [ECOG] score)
4. Platelets greater than 50,000/mm^3
5. Prothrombin time (quick) greater than 60%
6. White blood cells greater than 2500/mm^3
7. Life expectancy greater than 6 months

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
750 patients

Key exclusion criteria
1. Severe hepatic failure (ascites, portal hypertension, jaundice or encephalopathy)
2. Renal failure (haemodyalisis and creatinine greater than 2.5 mg/dL)
3. Active infections
4. Coagulopathy
5. Inability to give an informed consent

Date of first enrolment
01/07/2003

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
Italy

Study participating centre
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Sponsor information

Organisation
European Institute of Oncology (Italy)

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Sponsor type
Research organisation

Website
http://www.ieo.it/inglese/index.asp

ROR
https://ror.org/02vr0ne26

Funder(s)

Funder type
Research organisation

Funder Name
Italian Association for Cancer Research (Italy) (ref: 1126)

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