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# PORT-cAtheter-System implantation: a randomised controlled trial to compare two different surgical implantation techniques

**Submission date**
13/12/2005

**Recruitment status**
No longer recruiting

**Registration date**
07/02/2006

**Overall study status**
Completed

**Last Edited**
03/02/2009

**Condition category**
Surgery

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
KSC 02/2005

## Study information

**Scientific Title**

## Acronym
PORTAS

## Study objectives
The primary objective is to show whether a modified Seldinger technique is superior to the conventional surgical approach in implanting a port-catheter-system with less failures than the prior strategy. The modified Seldinger technique consists of a set including an introducer, a guide wire and a pull-away-sheath to place the catheter correctly.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Local Ethics Commission approved 12th December 2005

## Study design
Single-centre intra-operatively randomised controlled superiority trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Port-catheter-system implanting

## Interventions
Patients with benign or malignant diseases who demand a safe and permanent venous access e. g. for chemotherapy and/or parenteral nutrition, will be randomised to:
Group 1: A modified Seldinger-technique with a guide wire, dilatator and a pull-away-sheath is used after preparation of the cephalic vein to place the catheter
Group 2: Conventional venae section technique is used. The catheter will be inserted directly without a pull-away-sheath or a guide wire.

Please note that this trial was successfully completed in May 2007.

## Intervention Type
Procedure/Surgery

## Phase
Not Applicable

## Primary outcome(s)
Primary success rate of both implantation techniques.

## Key secondary outcome(s))
1. Duration of the procedure
2. Rate of peri- or post-operative complications

### Completion date
01/06/2007

## Eligibility

### Key inclusion criteria
1. Aged 18 years or more, either sex
2. Patients scheduled for primary elective implantation of a port-catheter-system under local anaesthesia
3. Informed consent

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Key exclusion criteria
1. Participation in another interventional-trial with possible interference in the outcome or interventions in this study
2. Lack of compliance
3. Impaired mental state or language problems

### Date of first enrolment
01/01/2006

### Date of final enrolment
01/06/2007

## Locations

### Countries of recruitment
Germany

### Study participating centre

**Department of Surgery**
Heidelberg
Germany
69120

# Sponsor information

**Organisation**
University of Heidelberg (Germany)

**ROR**
https://ror.org/038t36y30

# Funder(s)

**Funder type**
University/education

**Funder Name**
University of Heidelberg (Germany) - Department of Surgery

# Results and Publications

## Individual participant data (IPD) sharing plan

**IPD sharing plan summary**
Not provided at time of registration

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/02/2009 | | Yes | No |
| Protocol article | protocol | 08/06/2006 | | Yes | No |