

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

<b>Submission date</b> 13/12/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 07/02/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 03/02/2009	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

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

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Markus W. Buechler

**Contact details**  
Department of Surgery  
University of Heidelberg  
Im Neuenheimer Feld 110  
Heidelberg  
Germany  
69120  
+49 (0)6221 566200  
Markus.Buechler@med.uni-heidelberg.de

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

# 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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## 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 measure**

Primary success rate of both implantation techniques.

**Secondary outcome measures**

1. Duration of the procedure
2. Rate of peri- or post-operative complications

**Overall study start date**

01/01/2006

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

160 patients

**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)

**Sponsor details**

Department of Surgery

Im Neuenheimer Feld 110

Heidelberg

Germany

69120

+49 (0)6221 566200

Markus.Buechler@med.uni-heidelberg.de

**Sponsor type**

University/education

**ROR**

<https://ror.org/038t36y30>

## Funder(s)

**Funder type**

University/education

## Funder Name

University of Heidelberg (Germany) - Department of Surgery

## 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

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	08/06/2006		Yes	No
<a href="#">Results article</a>	results	01/02/2009		Yes	No