

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	☐ Prospectively registered ☒ Protocol
Registration date 07/02/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 03/02/2009	Condition category Surgery	☐ 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