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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	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 07/02/2006	**Overall study status** Completed	
Last Edited 03/02/2009	**Condition category** Surgery	

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

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

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)

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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?
Protocol article	protocol	08/06/2006		Yes	No
Results article	results	01/02/2009		Yes	No