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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
13/12/2005		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
07/02/2006	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
03/02/2009	Surgery			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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. q. 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 recruitmentGermany

Study participating centre
Department of Surgery
Heidelberg
Germany
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Sponsor information

Organisation

University of Heidelberg (Germany)

Sponsor details

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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