The aim of this trial is to identify the strategy for the implantation of TIVAPs with the lowest risk of pneumothorax and haemothorax" Hüttner et al (2015).

Reference:

Hüttner, F.J., Bruckner, T., Alldinger, I., Hennes, R., Ulrich, A., Büchler, M.W., Diener, M.K. and Knebel, P. (2015) Frequency of pneumothorax and haemothorax after primary open versus closed implantation strategies for insertion of a totally implantable venous access port in oncological patients: study protocol for a randomised controlled trial.Trials. 16(128).

Open versus closed implantation strategies for vascular access port insertion http://ctt.ec/lmQVb+ @ivteam #ivteam

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Abstract:

BACKGROUND: The insertion of central venous access devices, such as totally implantable venous access ports (TIVAPs), is routine in patients who need a safe and permanent venous access. The number of port implantations is increasing due to the development of innovative adjuvant and neo-adjuvant therapies. Currently, two different strategies are being routinely used: surgical cut-down of the cephalic vein (vena section) and direct puncture of the subclavian vein. The aim of this trial is to identify the strategy for the implantation of TIVAPs with the lowest risk of pneumothorax and haemothorax.

METHODS/DESIGN: The PORTAS-3 trial is designed as a multicentre, randomised controlled trial to compare two implantation strategies. A total of 1,154 patients will be randomised after giving written informed consent. Patients must be over 18 years of age and scheduled for primary implantation of a TIVAP on the designated side. The primary endpoint will be the frequency of pneumothorax and haemothorax after insertion of a TIVAP by one of two different strategies. The experimental intervention is as follows: open strategy, defined as surgical cut-down of the cephalic vein, supported by a rescue technique if necessary, and in the case of failure, direct puncture of the subclavian vein. The control intervention is as follows: direct puncture of the subclavian vein using the Seldinger technique guided by sonography, fluoroscopy or landmark technique. The trial duration is approximately 36 months, with a recruitment period of 18 months and a follow-up period of 30 days.

DISCUSSION: The PORTAS-3 trial will compare two different TIVAP implantation strategies with regard to their individual risk of postoperative pneumothorax and haemothorax. Since TIVAP implantation is one of the most common procedures in general surgery, the results will be of interest for a large community of surgeons as well as oncologists and general practitioners. The pragmatic trial design ensures that the results will be generalizable to a wide range of patients.

TRIAL REGISTRATION: The trial protocol was registered on 28 August 2014 with the German Clinical Trials Register (DRKS00004900) . The World Health Organization’s Universal Trial Number is U1111-1142-4420.

Full Text

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