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Study Summary
Clinical Investigation of pfmmedical Implantable Vascular Access Ports

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pfmmedical Implantable Vascular Access Ports: Clinical Use and Patient Satisfaction

A prospective, monocentric, non-randomised, observational study

Background

Implantable vascular access ports facilitate repeated vascular access intended for the delivery of medications, intravenous fluids, parenteral nutrition solutions or blood products and blood sampling. To obtain post-market information on pfmmedical implantable vascular access ports, a prospective, monocentric, non-randomised, observational Post-Market Clinical Follow-up Study was performed at the Heidelberg University Hospital with a follow-up of six months between March 2022 and September 2023 focusing on patient reported satisfaction, clinical application and complication rates.

Method

The main objectives of the clinical study (NCT05209828, DRKS00026150) were to confirm the clinical performance of pfmmedical port systems with respect to safety of the applied devices and positive effects on patients' quality of life (QoL). The primary endpoint was the evaluation of difference between four satisfaction scores from six-months post-study treatment and the current literature. This is defined by the four domains satisfied overall, choose port again, cosmetic results and pain of the validated patient questionnaire on satisfaction and QoL by Nagel et. al. (2012), measured at the six-months follow-up.

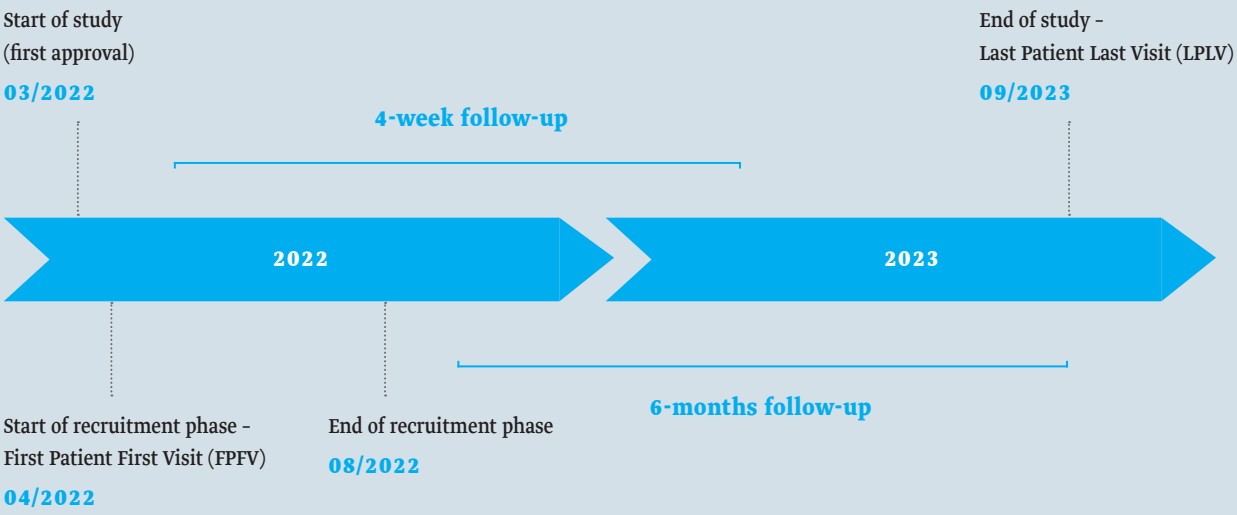
Results

In total, 149 patients were selected for this study according to inclusion and exclusion criteria as stated in the instructions for use and implanted with a pfmmedical port system based on the indication for the need of continuous venous access. Study and safety data was collected at screening, operation, discharge and at a four-week and six-months follow-up. Patients had a mean age of 58.8 years, ranging from 19 to 85 years. 41 out of 149 patients reported previous usage of a Central Venous Catheter (CVC). The main surgical method used for implantation was venae sectio (78.5%) followed by the Modified Seldinger Technique (18.1%) with access vessels being the vena cephalica in 126 cases, vena subclavia in 4 cases and vena jugularis interna, vena jugularis externa as well as vena femoralis in 2 cases respectively. The port system was used mostly for chemotherapy (67.1 %) and blood sampling (37.6 %). The multiple use of ports related to the application of substances (e.g. chemotherapeutic agents) and blood sampling is common. Overall, 117 patients completed the six-months follow-up. Concerning the study hypothesis, patient satisfaction was non-inferior to the reference value of the comparison literature in all four endpoint-related domains from the validated questionnaire: Overall satisfaction (18.5 vs. 35.6; $p < .001$), the willingness to choose the port again (15.8 vs. 29.4; $p < .001$), the cosmetic result (38.0 vs 39.9; $p = .003$), and whether the port was painful for the patient (17.1 vs 31.5; $p < .001$). A total of 44 adverse events occurred during the study, the procedure relevant occurrences were infection (8), thrombosis (4), hematoma (2), wound infection (2), bleeding (1), cardiac arrhythmia (1) and wound healing disorder (1).

Conclusions

Study results allow for the conclusion to be drawn that the use of pfmmedical port systems for repeated vascular access has a positive impact on patient satisfaction and patients benefit from a good quality of life and low complication rates. With regards to adverse events (AE), the assessment of occurrence and type of AE during the study showed similar rates compared to current literature. Safety investigations revealed the occurrence of complications in 21 out of 149 patients resulting in an overall complication rate of 14.09 %. No unexpected causal relationship between AE and the investigational product or implantation procedure could be identified.

Timeline



Study Centre:

Heidelberg University Hospital
Im Neuenheimer Feld 672
69120 Heidelberg, Germany

Coordinating Investigator: Prof. Dr. med. Phillip Knebel

Investigational Products:

- Jet Port® Plus II Contrast (REF 61.635.73.077)
- T-Port Contrast (REF 61.635.53.077)
- T-Port Low Profile Contrast (REF 61.635.63.077)

Contact

Should you have any questions our Regulatory and Clinical Affairs Team will be glad to advise you.

pms@pfmmedical.com +49 2236 9641-99272

pfm medical gmbh
Wankelstraße 60
50996 Köln
Germany

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