



Klinik und Poliklinik für Allgemein-, Viszeral- und Thoraxchirurgie

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Statement of the Coordinating Investigator

The NEOPA trial was terminated prematurely due to unexpectedly low recruitment. Despite great efforts, the recruitment of 410 patient could not be achieved. Finally, only 30 patients were enrolled in about three years and at 16 study sites. The reasons for the lack of recruitment leading to the termination are certainly diverse; in addition to the overestimated total number of patients who could be screened, the rate of consenting patients was also significantly lower than expected. Unfortunately, the patients could not be sufficiently convinced of a neoadjuvant concept. Another factor from the point of view of the study management is that more and more competing studies have been initiated in the last few months which allegedly pursue more modern neoadjuvant concepts, so that the focus of the participating centers evidently moved even further away from the NEOPA study.

Due to the low recruitment and early termination no efficacy analysis was feasible and no robust and statistically analysable data regarding the safety of the therapy were generated. Therefor, no scientific reliable conclusion can be drawn.

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