

Title: Comparison of traditional back-loaded fiducial needles with preloaded fiducial needles in EUS-guided fiducial marker placement for image-guided radiation therapy in patients with pancreatic cancer: A multicenter randomized controlled trial.

NCT02332863

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Statistical Analysis Plan

The sample-size calculation was based on limited experimental data in a porcine model, and on a consensus decision among expert endosonographers regarding the relative reduction in the time (60%) to deploy preloaded fiducial markers¹⁸. We estimated that a sample size of 40 patients (20 in each arm) was needed to provide the study with at least 80% power and a 2-sided alpha of 0.05. All analyses were performed according to the intention-to-treat principle. Per-protocol analysis was also performed. Descriptive statistics are reported as absolute values (percentage), mean \pm standard deviation, and median (IQR), as appropriate. Comparisons of baseline characteristics and outcomes were evaluated using chi-square or Fischer exact test for categorical data and Student t test or Mann-Whitney U test for continuous data. Pre-established subgroup analysis was performed by tumor location (head/neck vs body/tail). Although not pre-established in the study protocol, results were also stratified by time of randomization (first half vs second half) to explore a possible learning curve effect. Statistical significance was defined as $P < .05$. All statistical analyses were performed using Stata/ IC version 12.1 (College Station, TX).

References:

18. Draganov P.V., Chavalitdhamrong D., and Wagh M.S.: Evaluation of a new endoscopic ultrasound-guided multi-fiducial delivery system: a prospective non-survival study in a live porcine model. *Dig Endosc* 2013; 25: pp. 615-621