

EUS-FNB with or without on-site evaluation for the diagnosis of solid pancreatic lesions (FROSENOR): Protocol for a multicenter randomized non-inferiority trial

Stefano Francesco Crinò¹, Ermina Manfrin², Aldo Scarpa³, Francisco Baldaque-Silva⁴, Silvia Carrara⁵, Germana De Nucci⁶, Roberto Di Mitri⁷, Angel Ginés⁸, Julio Iglesias-Garcia⁹, Takao Itoi¹⁰, Masayuki Kitano¹¹, Nam Quoc Nguyen¹², Pierre H Deprez¹³, Jan-Werner Poley¹⁴, Vanessa M Shami¹⁵, Ilaria Tarantino¹⁶, Alberto Larghi¹⁷

Affiliations + expand

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Abstract

Background: Rapid on-site evaluation (ROSE) of cytological specimens acquired with EUS-guided fine needle aspiration (EUS-FNA) represents the most accurate available technique to reach a definitive diagnosis in patients with pancreatic solid masses. Recently, needles with high histological yield have been developed for EUS-guided fine needle biopsy (EUS-FNB), with which the need for ROSE can be potentially overcome.

Aims: The primary aim is to compare the diagnostic accuracy of EUS-FNB with or without ROSE. The main endpoint will be measured against the gold standard diagnosis (surgical pathology whenever available or diagnostic work-up in agreement with a clinical course of at least six months). Secondary endpoints include: (a) safety; (b) presence of tissue core; (c) quality of specimens; (d) time of the sampling procedure. Reliability of macroscopic on-site evaluation (MOSE) by endosonographers will be also assessed.

Methods: FROSENOR is an international randomized non-inferiority ongoing study at sixteen centers in four continents. Eight hundred patients will be randomized in two arms (EUS-FNB + ROSE vs. EUS-FNB alone) and outcomes compared. Sample size has been calculated in order to demonstrate the non-inferiority of FNB alone. Randomization and data collection will be performed online.

Discussion: This study will ascertain if ROSE is still needed when performing EUS-FNB of solid pancreatic lesions.

Keywords: Diagnostic accuracy; Endoscopic ultrasound; Pancreatic cancer.