**Study protocol**

# A Multicenter Randomized Trial, Comparing a 25G EUS Fine Needle Aspiration (FNA) Device with a 20G EUS ProCore Fine Needle Biopsy (FNB) Device

**ASPRO trial** (**ASP**iration versus **PRO**core)

**ProCore study group**

**PROTOCOL TITLE**

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| **Protocol ID** | ASPRO trial |
| **Short title** | Comparing a 25G EUS-FNA with a 20G EUS ProCore FNB Device |
| **Version** | Version 1 |
| **Date** | 13-10-2014 |
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| **Laboratory sites** | Department of Clinical Pathology, Erasmus University Medical Center, Rotterdam, the Netherlands |
| **Pharmacy** | Not applicable |


## SUMMARY

**Rationale:** During Endoscopic Ultrasound (EUS), tissue samples can be obtained with different techniques. Fine needle aspiration (FNA) provides a cytological specimen. With fine needle biopsy (FNB), a histological specimen is obtained, which generally results in a better diagnostic performance. However, FNB needles are stiffer and more difficult to handle, and can therefore result in less tissue acquisition.

**Objectives**: To compare the performance and diagnostic accuracy of two EUS-guided tissue acquisition devices; a 25G Echotip Ultra Fine Needle Aspiration (FNA) device and a new, more flexible 20G Echotip ProCore Fine Needle Biopsy (FNB) device.

**Study design:** International randomized multicenter trial.

**Study population:** Patients ≥18 years old, referred for EUS-guided tissue sampling of a: (I) pancreatic mass lesion, (II) lymph node, or (III) other submucosal or undefined mass (non-pancreatic), ≥ 1 cm in size.

**Intervention:** EUS-guided tissue acquisition by means of either the 25G Echotip Ultra FNA device, or the 20G Echotip ProCore FNB device.

**Main study parameters/endpoints:** The main endpoint is the diagnostic performance, measured against the ***gold standard*** diagnosis (based on the surgical resection specimen or in non-operated patients, the outcome of the diagnostic work-up (i.e. tissue sampling and imaging studies), confirmed by a compatible clinical disease course). Secondary endpoints include I. technical success, II, specimen specifics, such as; quality, presence of tissue cores, and pathological classification (cytology, cell-block, or histology), III. procedural aspects, such as; safety, the yield of a single needle pass, and the value of on-site pathological evaluation, and IV. inter-observer variation.

**Nature and extent of the burden and risks associated with participation, benefit and group relatedness:** There are no additional risks involved. Patients are referred for EUS-guided tissue acquisition, as part of the standard diagnostic work-up. Previous reports showed EUS-guided FNA and FNB sampling to be equally safe.