Prostate HistoScanning for the Detection, Localization and Volume Estimation of Prostate Cancer: PHS02

Introduction and Objective: Prostate HistoScanning uses the unprocessed ultrasound data from 3D transrectal scanning and after further processing, predicts the presence or absence of prostate cancer and the 3D location of the cancer within the gland. Initial proof of concept studies (1;2) and the open phase of this study (3) exhibited promising sensitivity and specificity of Prostate HistoScanning for detection of clinically significant prostate cancer. We report the design and recruitment to the larger, STARD compliant, European multicentre study - PHS02.
Materials and Methods: Eligible patients comprised men scheduled for radical prostatectomy and consented to the acquisition of a 3D TRUS study of the prostate prior to surgery (the index test). 3D TRUS data files underwent spectral analysis using HistoScanning software blinded to the pathology results. Radical Prostatectomy (the reference test) specimens were processed centrally at an independent laboratory to a precise standard operating procedure with whole-mount 3-4mm slices. . Further analysis was performed in 5x5mm grid analysis of each whole-mount pathology section. Pathological processing was performed blind to the results of the HistoScanning analysis with matching between index and reference test undertaken by an independent committee. Accuracy will be calculated on detection of prostate cancer foci greater than or equal to 0.5cc and 0.2cc in volume in each of six sectors of the prostate.
Results: Number of patients screened, recruited and excluded are shown in figure 1. Results are anticipated mid-2012.
Conclusion: The results of this STARD compliant, blinded, multi-centre study of HistoScanning are awaited. Many of the methodological problems associated with testing an index test against radical prostatectomy as a reference test are pertinent to other studies seeking to evaluate the role of imaging tests in the prostate cancer diagnostic pathway.

Figure 1: Recruitment to Blind Phase verification phase