C-ProMeta-1: Predicting treatment failure after radical prostatectomy using circulating tumour cells

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Background & objectives

Treatment decisions in prostate cancer (PCa) rely on classifying patients between localized and metastatic stages. However, current imaging tools are not sensitive to detect low volume metastasis. The presence of circulating tumour cells (CTCs) may predict metastatic disease before lesions are detectable using conventional imaging. We have previously demonstrated that CTCs alongside prostate specific antigen (PSA) could predict biopsy results in a cohort of pre-biopsy PCa patients. This study aims to evaluate the accuracy of CTCs to predict treatment failure after radical prostatectomy (RP).

This clinical trial will investigate the value of CTCs in predicting treatment failure in high-risk patients with localized prostate cancer undergoing RP. We present here the study protocol and preliminary patient recruitment data.

Methods

Patients diagnosed with high-risk, localized PCa who are scheduled for RP are eligible. Those with co-occurring malignancies, or previous PCa treatment are excluded. Fifteen milliliters of whole blood will be collected for CTC analysis (CTC enumeration and RNA analysis) before surgery and 3 months post-surgery. Matched pre- and post-surgery samples will be obtained from 200 patients in 2 years. CTCs will be isolated from 7.5ml blood using the Parsortix system. Immunofluorescence analysis will identify CTCs based on epithelial and mesenchymal markers. CTC gene expression will be measured using Hyzip multiplex technology. Patients will be followed up after surgery for at least 4.5 years. Diagnosis of metastatic lesions using imaging, or a PSA $\geq$ 0.2 mg/ml is defined as treatment failure.

Results

The first patient was recruited in February 2022 and to date, 169 patients have been recruited and blood samples taken prior to surgery. Post-surgery blood samples have been obtained for 90 patients (53%). Immunofluorescence staining for CTCs has been carried out on 100% of samples and CTC RNA has been isolated from 98% of samples.

Conclusion

We will determine whether a test for CTC detection alone and in combination with CTC RNA expression can predict treatment failure at the time of surgery (and after) in these patients. The results may allow for better risk stratification and identify patients who would benefit from adjuvant treatment.