

**CoRIPS study 124: Comparison of Double Inversion Recovery Magnetic Resonance imaging (DIR-MRI) and Dynamic contrast Enhanced Magnetic Resonance Imaging (DCE-MRI) in Detection of Prostate Cancer: A Pilot Study.**

**Interim Report**

**The principle aim** of this pilot study was to gather data from DIR-MRI and DCE-MRI of the prostate, to inform a sample size calculation for a fully powered equivalence trial. This will enable us to assess whether there is equivalence between DIR-MRI and DCE-MRI in the detection of prostate cancer.

**Primary Research question**

Is DIR-MRI equivalent to DCE-MRI in the detection of prostate cancer: A pilot study to determine sample size?

**Secondary Research questions**

Does the addition of DIR-MRI improve accuracy of cancer diagnosis?

**Method**

**Quantitative pilot study comparing DCE-MRI with DIR-MRI for equivalence, in detection of Prostate Cancer**

150 participants were recruited to the study. They were offered the non-invasive DIR-MRI, in addition to standard care. Therefore all participants had DIR-MRI prior to DCE-MRI scan. DICOM images were reviewed on the PACS system by an experienced Consultant Radiologist (more than 5 years' experience in prostate MRI reporting). He was shadowed by a novice reporter to identify a Region of Interest (ROI) within a suspected cancer and within a normal looking prostate using a freehand technique. The potential cancer lesions in the prostate were quantified using a lesion to normal background prostate signal ratio (LNR). The average signal returned from within the lesion and from the normal tissue was recorded. The process was repeated for each of the sequences.

The LNR for each sequence was calculated. Exploratory analysis was considered to determine the accuracy of cancer diagnosis using the standard combination of images with DCE-MRI and DIR-MRI which was compared with biopsy results.

**Initial Findings**

This pilot study has provided necessary data to calculate a sample size for a subsequent study which will assess whether there is equivalence between DIR-MRI and DCE-MRI in the detection of prostate cancer.

The study has added to the understanding of DIR-MRI and particularly how best to perform it for the most useful images of the prostate. It has demonstrated what normal and abnormal prostate look like on DIR-MRI.

There will be cost and time saving if DIR-MRI replaces DCE-MRI in mpMRI of the prostate. Larger studies are needed to confirm the link between DIR and DCE, but the results could offer help for people in whom contrast cannot be used.

**Initial Observations**

The estimated 45 patient with definite cancer for sample size was achieved. DIR-MRI may be equivalent to DCE-MRI in prostate cancer detection. There will be cost and time saving if DIR-MRI replaces DCE-MRI in mpMRI of the prostate. Patients who cannot have contrast agent or decline the administration of contrast can have their prostate accurately evaluated, reducing associated contrast risks such as kidney disease.

**Work outstanding**

- Analysing the data further to produce the final report and recommendations
- Writing an article for the peer-reviewed Radiography journal

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