Clinical trial will test use of MRI to improve prostate cancer diagnosis and management

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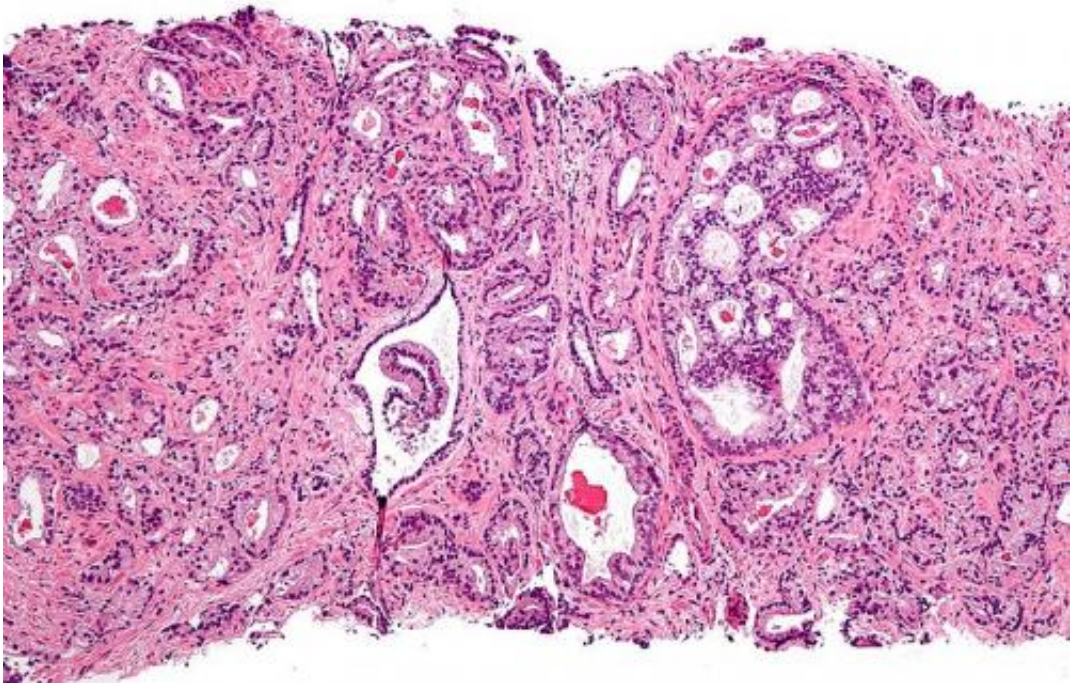

Micrograph showing prostatic acinar adenocarcinoma (the most common form of prostate cancer) Credit: Wikipedia, CC BY-SA 3.0

The Movember Foundation, the Ontario Institute for Cancer Research (OICR) and Prostate Cancer Canada today announced $3 million in funding for a new Phase III clinical trial to evaluate if magnetic resonance imaging (MRI) can replace the current standard of care to diagnose prostate cancer. The primary objective of the multi-centre trial, called PRECISE, is to determine whether MRI imaging can spare some

men from undergoing a biopsy and avoid the possible associated side effects.

The trial will be led by Dr. Laurence Klotz of the Sunnybrook Research Institute in Toronto, a world leader in the field of prostate cancer research and in the global adoption of active surveillance, a standard practice to monitor patients with low risk prostate cancer.

MRI technology is a precise tool that could better identify which patients should undergo biopsy, and enable targeted biopsy of only areas suspected of malignancy. The PRECISE trial, which is estimated to be completed in three years, will investigate the ability of MRI to improve the diagnosis of clinically important disease and reduce the requirement for prostate biopsies. Currently, prostate cancer is diagnosed by trans-rectal ultrasound (TRUS)-guided biopsy of the prostate, in most cases following a Prostate Specific Antigen (PSA) test. TRUS-guided biopsy is associated with potential side effects such as infection and bleeding because it is not targeted, requiring numerous biopsy samples (between 10 and 12) to establish an accurate reading. In addition, this current standard of care is not sensitive enough to be able to discriminate between high-risk and very low-risk changes in prostate tissue, resulting in the over-diagnosis and over-treatment of many men, exacerbating the risk for side effects.

"If positive, this trial would support a change in practice from relying on biopsies for all men with suspected prostate cancer to providing MRI first with selective targeted biopsy," explained Klotz. "This would allow 250,000 men per year in the U.S. and Canada to avoid unnecessary biopsies and the associated complications including hospitalization, without compromising our ability to identify clinically significant cancers."

"One of the strategic priorities of OICR is to improve the management

of patients with early prostate cancer, to avoid over-diagnosis while ensuring men with prostate cancer get the treatment they need," said Dr. Lincoln Stein, Interim Scientific Director of the Ontario Institute for Cancer Research. "Using MRI technology to image the prostate before biopsy will help reduce the number of unnecessary biopsies and their associated complications, while ensuring maximum precision for guiding the biopsy when and where it is really needed. Along with our partners at Movember and Prostate Cancer Canada, we are proud to support this trial and look forward to seeing the results in the clinic."

"The Movember Foundation continually looks to stay true to one of our core values in constructive disruption—being prepared to take risks and use novel approaches to solving problems. We recognize this investment is in line with not only that, it also seeks to achieve the core pillars of our investment strategy in leading to the avoidance of unnecessary treatment and to lead to minimally invasive tests," said Movember Canada's Jon Tower Akerman, adding, "We're proud to see that our partners agree, innovation matters."

Data management and analysis for the trial will be conducted by the Ontario Clinical Oncology Group (OCOG) in the Escarpment Cancer Research Institute, a Hamilton Health Sciences and McMaster University institute. "We are excited about collaborating with Dr. Klotz on the evaluation of this innovative technology which could potentially impact the lives of thousands of Canadian men," said Dr. Mark Levine, Director of OCOG.

"Approximately 20 years after PCC helped fund Dr. Klotz' watchful observation study, hundreds and hundreds of men with low-risk prostate cancer have had an option to avoid unnecessary treatment," said Dr. Stuart Edmonds, PCC's vice-president of Research and Health Promotion. "We're proud to join Movember and OICR to support Dr. Klotz' work aimed at ensuring men will also have an option to greatly

reduce the risks associated with biopsies."

Dr. Klotz is a physician and researcher based at the Sunnybrook Health Sciences Centre in Toronto. He is also a professor at the University of Toronto and the Chair of the World Urologic Oncology Federation. Last month he was invested as a Member of the Order of Canada.

Provided by Ontario Institute for Cancer Research