Clinical trial registration: This study is registered at ClinicalTrials.gov. The registration identification number is NCT00676286.
(https://clinicaltrials.gov/ct2/show/NCT00676286)

Corresponding Author

Nawaid Usmani

Signature: _____ **Date:** November 16, 2015

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Biological Investigations in Active Surveillance (BIAS) IGAR 2008 I 19 in Prostate Cancer Using High Field MRI (3 Tesla), PET, and Biomarkers

This study is ongoing, but not recruiting participants.

Sponsor:
AHS Cancer Control Alberta

Information provided by (Responsible Party):
AHS Cancer Control Alberta

ClinicalTrials.gov Identifier:
NCT00676286

First received: May 12, 2008
Last updated: March 31, 2014
Last verified: March 2014
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Tracking Information	
First Received Date ICMJE	May 12, 2008
Last Updated Date	March 31, 2014
Start Date ICMJE	November 2008
Estimated Primary Completion Date	August 2014 (final data collection date for primary outcome measure)
Current Primary Outcome Measures ICMJE **(submitted: May 12, 2008)**	Primary objective to determine if we can accrue patients to this study in a timely manner. [Time Frame: 2 years] [Designated as safety issue: No]
Original Primary Outcome Measures ICMJE	*Same as current*
Change History	Complete list of historical versions of study NCT00676286 on ClinicalTrials.gov Archive Site
Current Secondary Outcome Measures ICMJE **(submitted: May 12, 2008)**	• Patient compliance [Time Frame: Patients followed for 5 years from baseline] [Designated as safety issue: No] • Optimal imaging parameters to characterize prostate cancers [Time Frame: patients followed for 5 years from baseline] [Designated as safety issue: No] • feasibility of detecting gene arrangements in prostate biopsies [Time Frame: patients followed for 5 years from baseline] [Designated as safety issue: No] • Incidence of patients developing progressive prostate cancer warranting definitive treatment in an active surveillance protocol [Time Frame: patients followe for 5 years from baseline] [Designated as safety issue: No] • The natural history of prostate cancer with these investigations [Time Frame: patients followed for 5 years from baseline] [Designated as safety issue: No] • The sensitivity and specificity of these investigation in detecting prostate cancer [Time Frame: patients followed for 5 years from baseline] [Designated as safety issue: No] • The sensitivity and specificity of these investigations in differentiating indolent prostate cancer from aggressive disease [Time Frame: patients followed for 5 years from baseline] [Designated as safety issue: No] • The sensitivity and specificity of these investigations in detecting high grade disease, extracapsular disease and extraprostatic disease and disease progression [Time Frame: patients followed for 5 years from baseline] [Designated as safety issue: No]

Original Secondary Outcome Measures ICMJE	*Same as current*
Current Other Outcome Measures ICMJE	*Not Provided*
Original Other Outcome Measures ICMJE	*Not Provided*

Descriptive Information

Brief Title ICMJE	Biological Investigations in Active Surveillance (BIAS) IGAR 2008 I 19 in Prostate Cancer Using High Field MRI (3 Tesla), PET, and Biomarkers
Official Title ICMJE	Biological Investigations in Active Surveillance (BIAS) IGAR 2008 I 19
Brief Summary	This study will use high field MRI (3 Tesla), PET and biomarker to follow prostate cancers and determine if these tests can detect cancers that become aggressive.
Detailed Description	This study may lead to the identification of additional investigations that can monitor for signs of disease progression in active surveillance protocols. This can directly benefit patients by providing them with greater confidence that their disease is being accurately monitored. In addition, this study may be beneficial to the general management of prostate cancers by adding to our knowledge of these investigations characterizing prostate cancers.
Study Type ICMJE	Interventional
Study Phase	Phase 1
Study Design ICMJE	Allocation: Non-Randomized Endpoint Classification: Efficacy Study Intervention Model: Single Group Assignment Masking: Open Label Primary Purpose: Screening
Condition ICMJE	Prostate Cancer
Intervention ICMJE	• Procedure: 3T MR Imaging 3TR Imaging • Procedure: C-Choline PET Scanning C-Choline PET Scanning • Procedure: Gene Rearrangement Gene Rearrangement
Study Arm (s)	*Not Provided*
Publications *	*Not Provided*

*** Includes publications given by the data provider as well as publications identified by ClinicalTrials.gov Identifier (NCT Number) in Medline.**

Recruitment Information

Recruitment Status ICMJE	Active, not recruiting
Estimated Enrollment ICMJE	20
Estimated Completion Date	August 2014
Estimated Primary	August 2014 (final data collection date for primary outcome measure)

Completion Date	
Eligibility Criteria ICMJE	Inclusion Criteria: • Histologically proven adenocarcinoma of the prostate • Registration must occur within 16 weeks of last biopsy • History and physical exam (including DRE) within 8 weeks prior to registration • Patients must have indolent prostate cancer including all of the following: Low risk prostate cancer, less or equal to 50 % of core biopsies involved with disease, and less or equal to three biopsies involved with disease • Patients must have a minimum of six biopsies (sextant) at registration • PSA test within 8 weeks registration • Creatinine level below 100 umol/L within 8 weeks of registration • Patients must have no contraindications to MRI scans • No history of previous malignancies except non-melanoma skin tumors or other malignancies with a greater than 5 year life expectancy • Patients must be reliable for follow up Exclusion Criteria: • Patient does not have histologically-proven adenocarcinoma of the prostate • Last biopsy greater than 16 weeks prior to registration • History and physical exam (including DRE) greater that 8 weeks prior to registration • Patient does not have indolent disease • Patient has less than six sextant biopsies at registration • PSA test done greater than 8 weeks from registration • Creatinine level greater than 100 umol/L within 8 weeks of registration • Contraindications to MRI scans • History of previous malignancies other than non-melanoma skin tumors or other malignancies with a greater than 5 year life expectancy • Patients that are not reliable for follow up
Gender	Male
Ages	18 Years and older
Accepts Healthy Volunteers	No
Contacts ICMJE	*Contact information is only displayed when the study is recruiting subjects*
Listed Location Countries ICMJE	Canada
Removed Location Countries	

Administrative Information

NCT Number ICMJE	NCT00676286
Other Study ID Numbers ICMJE	GU-24152
Has Data Monitoring Committee	Yes
Responsible Party	AHS Cancer Control Alberta
Study Sponsor ICMJE	AHS Cancer Control Alberta
Collaborators ICMJE	*Not Provided*
Investigators ICMJE	

	Study Chair:	Nawaid Usmani, MD, FRCPC	Cross Cancer Institute	
	Principal Investigator:	Nawaid Usmani, MD, FRCPC	Cross Cancer Institute	

Information Provided By	AHS Cancer Control Alberta
Verification Date	March 2014

ICMJE **Data element required by the International Committee of Medical Journal Editors and the World Health Organization ICTRP**