PROSTATE CANCER RESEARCH – MAKING A DIFFERENCE!

JULY 10, 2018
TYPES OF RESEARCH AT PCC

BENCH / TRANSLATIONAL RESEARCH

• “bench to bedside”

CLINICAL TRIAL - Scientific study involving humans

Interventional:

• Compares treatment options within a patient population
• Aim: To determine the efficacy and safety of two or more treatments

Non-Interventional:

• Observational Studies
• Aim: To gain further knowledge of how drugs are working and being used in everyday life
## Recruiting Studies

<table>
<thead>
<tr>
<th>Enrolment status</th>
<th>Enrolled</th>
<th>Investigators / Study</th>
<th>Key Inclusion Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open</td>
<td>PCC: 1848 (Goal: 8000)</td>
<td>Donnelly, et al. APCaRI – Evaluation of potential biomarkers to help the clinical management of prostate cancer</td>
<td>Pre-diagnosis (referred for biopsy) / Post-diagnosis of prostate cancer</td>
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<tr>
<td>Open</td>
<td>9 (Goal: 5)</td>
<td>Donnelly / Goto / Leong</td>
<td>HERO: A study to evaluate the safety and efficacy of relugolix in men with advanced prostate cancer</td>
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<tr>
<td>Open New May 1/18</td>
<td>12 (Goal: 10)</td>
<td>Gotto / Donnelly</td>
<td>GURC – Genitourinary Research Consortium, a multicenter study to document the course of advanced prostate cancer in Canada in terms of disease progression, real-world treatment, and patient management.</td>
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</tbody>
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### Ongoing studies (enrolment closed):

- **EMBARK**: 22 enrolled (Goal 5): Study of Enzalutamide plus Leuprolide, Enzalutamide Monotherapy, and placebo plus Leuprolide in men with high-risk nonmetastatic prostate cancer progressing after definitive therapy
- **ARAMIS**: 5 enrolled (Goal 5): Study of ODM-201 in men with high-risk non-metastatic castration-resistant prostate cancer (mCRPC)
- **COSMIC**: 39 Enrolled (Goal 10): Observational study of the use of Zytiga in clinical care of metastatic castration-resistant prostate cancer (mCRPC)
- **TITAN**: 11 Enrolled (Goal 5): Apalutamide plus Androgen Deprivation Therapy (ADT) Versus ADT Alone in Subjects with Metastatic Hormone Sensitive Prostate Cancer (mHSPC)
- **SPARTAN**: 6 enrolled (Goal 5): ARN-509 in men with non-metastatic castration-resistant prostate cancer (m0CRPC)
- **Enzamet**: 11 enrolled (Goal 5): Enzalutamide as 1st line therapy for men with hormone sensitive metastatic prostate cancer (mHSPC)
Recruitment and retention

Ground breaking results (Apalutamide)

Ongoing Program growth

- 1600 study patient visits conducted (2016 = 1200)
- Over 100 patients followed in 2017 for investigational treatments
- APCaRI: 500 additional patients in one year (Total = 1701)
ALBERTA PROSTATE CANCER REGISTRY AND BIORESPOSITORY (APCARI)

**Purpose:** To identify new ways of detecting and predicting serious prostate cancer

**Population:** 8800 men with confirmed prostate cancer or men scheduled for a biopsy

**Methods:** biological samples and health information collected yearly for 5 years
PHASES OF CLINICAL TRIALS
(ONCOLOGY EXAMPLE)
PHASES

- Clinical trials for new treatments are done through *Phases*.

- Each phase is designed to answer specific research questions

- The next phase can only start after the previous phase has shown to be safe and effective.

- There are several phases involved in a clinical trial:
PRE-CLINICAL

Wide doses of drug are tested:

• In vitro (test tube or cell culture)
• In vivo (animal)

PHASE 0

• Uses a very small dose of a drug to study the effects in a small group of people
• Tests how the drug is used by and affects the human body.
• Not used to gather information about the safety of the drug or its effectiveness in treating cancer.
PHASE I

• How the new treatment should be given, how often, what is the safest dosage

• What effect the drug or therapy has on the body

• What side effects people taking the drug or treatment experience

• Small group of people (about 10-15)
PHASE II

- Learn more about how effective a treatment is for a certain type of cancer

- Continue to evaluate how safe the drug is and what effect it has on the body

- Small group of people (usually less than 100) with one type of cancer
PHASE III

• Find out whether the treatment being tested is better, as good, or worse than the standard treatment
  • This includes evaluating quality of life and survival

• Compare side effects of the new treatment and standard treatment

• Involves a large number of people (hundreds to thousands) at several different locations
APPROVING A NEW DRUG OR TREATMENT

• After clinical trials show that a new drug or treatment for cancer is safe and effective, it is submitted to Health Canada for approval.

• Once approved, it can be recommended for treatment to people with cancer.

• It often takes more than 10 years for a new drug or treatment to go from preclinical trials, through clinical trials, to the approval process before it is available as a standard treatment to people with cancer.
PHASE IV

• Further evaluation of a drug after it has been approved for marketing

• Looks into risks and benefits in uncontrolled settings
Good Clinical Practice (GCP)

- An International ethical and scientific quality standard for conducting clinical trial
- Serves to protect the rights, integrity and confidentiality of trial subjects
- Provides a standard for countries to allow the mutual acceptance of clinical data

Examples:
- Clinical trials should be scientifically sound and described in a detailed protocol
- Informed consent must be obtained from every subject prior to clinical trial participation
CONDUCTING THE STUDY

Pre Screen Phase

Patient recruitment
- Identifying the Patient Population
- Referrals

First patient contact
- Physician discussion / Consent to review medical records
- Overview of study / Eligibility criteria assessment

Ongoing contact
- Send Informed Consent Document
- Book Screen Visit & Imaging appointments
CONDUCTING THE STUDY

Patient Visits

Types of Visits:

- Screen
- Enrolment
- On Treatment
- Long Term Follow Up