Study Schema

Registration

Surgery with Pancreaticoduodenectomy & Low Kilovoltage Intraoperative Radiation*

- 10Gy (3 Patients)
- 15Gy (3 Patients)
- 20Gy (6 Patients)

* Dose prescribed to the surface of tumor bed
Study Summary:

<table>
<thead>
<tr>
<th>Title</th>
<th>Phase I Study of Low Kilovoltage Intraoperative Radiation for Patients with Resectable Pancreatic Adenocarcinoma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short Title</td>
<td>Low kV IORT for Pancreatic Cancer</td>
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<tr>
<td>Protocol Number</td>
<td>N/A</td>
</tr>
<tr>
<td>Phase</td>
<td>Phase I</td>
</tr>
<tr>
<td>Methodology</td>
<td>Phase I Dose Escalation Design</td>
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<tr>
<td>Study Duration</td>
<td>36 months</td>
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<tr>
<td>Study Center(s)</td>
<td>Single Institution- Stritch School of Medicine, Loyola University Chicago</td>
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</tbody>
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Objectives

- **Primary objective:**
  1. To determine the dose limiting toxicity and maximum tolerated dose with low kilovoltage intraoperative radiation

- **Secondary objectives:**
  1. To develop acute and chronic clinical toxicity profiles for this treatment modality
  2. To determine clinical disease outcomes

| Number of Subjects | 12-18 |
| Diagnosis and Main Inclusion Criteria | Patients with pathologically confirmed pancreas cancer |
| | ECOG Performance status 0 or 1 |
| | Resectable disease as defined in section 3.1.4 |
| | Informed consent obtained prior to treatment |
| Exclusion Criteria | Treatment area unable to be adequately covered by radiation field |
| | Pregnancy or other comorbid conditions per Section 3.2.1 |
| Study Product(s), Dose, Route, Regimen | INTRABEAM Intraoperative Radiotherapy with flat applicator |
| Duration of administration | Single intraoperative administration |
| Statistical Methodology | Frequencies and percentages to describe dose limiting toxicities and adverse events (AEs) |
Eligibility:

1. Pathologically confirmed pancreatic adenocarcinoma.
2. $\geq$ 18 years.
3. Performance status ECOG 0-1.
4. Patient must have resectable disease
5. Stage I and stage II disease per AJCC 7th edition.
6. Complete history and physical examination including weight and ECOG performance status within 31 days of entry.
7. Laboratory data obtained $\leq$ 14 days prior to registration on study, with adequate bone marrow and organ function
8. Negative serum pregnancy test for females of childbearing potential within 14 days of study registration. Should a female participant become pregnant or suspect she is pregnant while participating in this study, she should inform her treating physician immediately.
9. Abdominal CT scan with contrast prior to performance of surgery. If patient is allergic to contrast an abdominal MRI may substitute. Other imaging may be added or substituted as deemed appropriate by the treatment team (surgeon, radiation oncologist, medical oncologist).
10. Patients with prior history of malignancy are permitted to register in the study as long as they are not actively taking cytotoxic or biologic medication for treatment of the prior malignancy. Patient must be disease-free from any malignancy for at least the previous 6 months and must have no history of brain metastases.
Phase I Study of Low Kilovoltage Intraoperative Radiation for Patients with Resectable Pancreatic Adenocarcinoma

Exclusion Criteria:

1. Defined treatment area which cannot be adequately covered by the radiation field as defined by the radiation oncology treatment team.
2. Patients who have received neoadjuvant chemotherapy are ineligible.
3. Patients with Stage III-Stage IV disease.
4. Patients who have been on an immunosuppressive agent (excluding corticosteroids) within 4 weeks of the proposed operation.
5. Patients receiving any other investigational agents.
6. Current pregnancy or currently nursing.
8. Severe, active comorbidity defined as follows
   - Unstable angina and/or congestive heart failure requiring hospitalization within the last 6 months. [23]
   - Myocardial infarction within 3 months of study registration [23]
   - Acute bacterial or fungal infection requiring intravenous antibiotics at the time of registration.
   - Chronic Obstructive Pulmonary Disease or other respiratory illness hospitalization or precluding study therapy at time of registration [23].
   - Uncontrolled diabetes which in the opinion of any of the patient’s physicians requires an immediate change in management. A patient may be considered eligible if the patient’s physician managing the diabetes deems the appropriate changes in management have resulted in adequate control. [23].
9. BMI >30.
10. Patient with active diagnosis of a bleeding disorder. [23]
11. Patients enrolled in another interventional clinical trial.