CONSIDERATIONS FOR AN OBSERVATIONAL STUDY: RADIAL VERSUS FEMORAL APPROACHES TO PCI

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**Hypothesis**

- Short-term and long-term reduction in bleeding and
- Reduction in vascular complications following PCI

- **Radial PCI**
- **Femoral PCI**
Hypothesis

RCT

SOURCES OF VARIATION

- PCI
  - Approach (radial versus femoral)
  - Stenting – BMS versus DES
- Short-term outcomes
  - Approach (radial versus femoral)
  - Patient characteristics
  - Operator (skill)
  - Center (environment, nursing team, etc)
- Long-term outcomes
  - Approach (radial versus femoral)
  - Patient characteristics
  - Compliance with anticoagulation therapy
- Adverse events
  - Procedural – radial (loss of use of arm)
<table>
<thead>
<tr>
<th>PCI Approach</th>
<th>Center 1</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Operator</td>
<td>Operator</td>
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</tr>
<tr>
<td>Radial</td>
<td>1</td>
<td>2</td>
<td>n₁</td>
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<tr>
<td></td>
<td>1</td>
<td>..</td>
<td>nₖ</td>
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<tr>
<td>Femoral</td>
<td>1</td>
<td>2</td>
<td>nₗ</td>
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</tbody>
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How well can we predict radial versus femoral PCI use?
Skill of operator to perform radial approach?
Accuracy of bleeding outcomes and complications.
Anticoagulation compliance post discharge?