Innovative Surgery Research Program
Gynecologic Oncology

Pedro T. Ramirez, M.D.
Professor
Director of Minimally Invasive Research & Education
Department of Gynecologic Oncology
Program Research Summary
Cervical Cancer

**Early-Stage**
2007-0800: A Phase III Randomized Trial of Laparoscopic or Robotic Radical Hysterectomy vs. Abdominal Radical Hysterectomy in Patients with Early Stage Cervical Cancer-Ramirez

2008-0118: Conservative Surgery for Women with Low-Risk, Early Stage Cervical Cancer-Schmeler

**Advanced-Stage**
2010-0952: A Phase III Randomized Study of Pretherapeutic Para-aortic Lymphadenectomy in Women with Locally Advanced Cervical Cancer Dispositioned to Definitive Chemoradiotherapy-Frumovitz
ConCerv

Kathleen M. Schmeler, MD
Associate Professor
Department of Gynecologic Oncology
ConCerv Trial

Inclusion Criteria:

- Stage IA2 or IB1 cervical cancer
- Tumor diameter ≤ 2 cm
- No LVSI
- ≤ 10 mm stromal invasion
- Squamous cell histology (any grade) or adenocarcinoma (grade 1 or 2 only)
- Cone margins and ECC negative for malignancy or CIN/AIS (one repeat cone/ECC permitted)
ConCerv Trial

- Patients desiring future fertility undergo cone and pelvic lymph node dissection
- Patients not desiring future fertility undergo simple hysterectomy and pelvic lymph node dissection
- Patients who had a cut-through simple hysterectomy are also eligible
ConCerv Trial

- Sample size: 100 patients

- **Stopping Rules:**
  - Residual disease in the hysterectomy specimens of $\geq 2$ patients
  - If $\geq 2$ patients develop recurrent disease
ConCerv – Participating Sites

- MD Anderson, USA (K. Schmeler)
- IDC, Colombia (R. Pareja)
- INCAN, Mexico (D. Cantu)
- Barretos, Brazil (J. Humberto-Fregnani)
- INEN, Peru (A. Lopez)
- Instituto de Onco, Argentina (M. Riege)
- Hospital Italiano, Argentina (M. Perrotta)
- Royal Women’s, Australia (O. McNally)
ConCerv - Results

- Sample size is 100 patients
- 102 patients pre-enrolled
- 53 eligible after MDACC pathology review
  - 25 simple hysterectomy + nodes (47%)
  - 16 cone + nodes (31%)
  - 8 cut-through hysterectomy (15%)
  - 2 surgeries pending (3%)
  - 1 cancelled due to + pregnancy test (2%)
  - 1 declined surgery (2%)
ConCerv – Accrual by Site

Accrual

- Colombia: 30%
- MD Anderson: 43%
- Peru: 11%
- Argentina: 10%
- Brazil: 2%
- Mexico: 2%
- Australia: 2%
ConCerv – Preliminary Results

• 3 patients with positive nodes (5.7%)

• One recurrence (1.9%):
  – Deep stromal invasion and CIN3 at margins
  – Inclusion criteria changed

• One patient with residual disease at hysterectomy (1.9%):
  – Multiple previous cones for AIS
  – No changes to inclusion criteria
A Phase III Randomized Clinical Trial Comparing Laparoscopic or Robotic Radical Hysterectomy with Abdominal Radical Hysterectomy in Patients with Early Stage Cervical Cancer


N=740
International Collaboration

End points:
  DSF
  Recurrence rate
  Overall survival
  Treatment-related morbidity
  QOL
  Lymphatic mapping feasibility
Secondary Objectives

• Patterns of recurrence

• Treatment-associated morbidity within 6 months from surgery

• Cost effectiveness (TLRH or TRRH versus TARH)

• Impact on Quality of Life (QoL)

• Assess pelvic floor function

• Overall survival between arms

• Feasibility of sentinel lymph node biopsy
LACC Consort Statement as at 20th April 2015

Assessed for Eligibility
n= 808

Pending
n = 0

Excluded n = 432
Not meeting eligibility criteria (n = 223)
Refused (n = 165)
Other (n = 38)
SHAPE Trial (n = 6)

Randomised
n = 377

Allocated to TARH
n = 183

Allocated to TLRH/TRRH
n = 194
Primary Endpoints

1. Overall survival
2. Disease Free Survival

Secondary Endpoints

1. Quality of Life
2. Surgical/Radiation Complications
3. Cost Effectiveness
4. Anatomical location of Positive Nodes
LiLACS Study Schema

Stages IB2-IVA

PET/CT Scan

Positive Pelvic/Negative PA Nodes

RANDOMIZE

Laparoscopic PALND Chemo-XRT

Pelvic Chemo-XRT
LiLACS Update

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Aim</td>
<td>600</td>
</tr>
<tr>
<td>Recruited</td>
<td>38</td>
</tr>
<tr>
<td>Refused</td>
<td>4</td>
</tr>
<tr>
<td>Recruiting sites</td>
<td>3</td>
</tr>
<tr>
<td>Pending</td>
<td>28</td>
</tr>
</tbody>
</table>