Cervical Cancer Updates
Global Gynecologic Oncology Consortium
G-GOC

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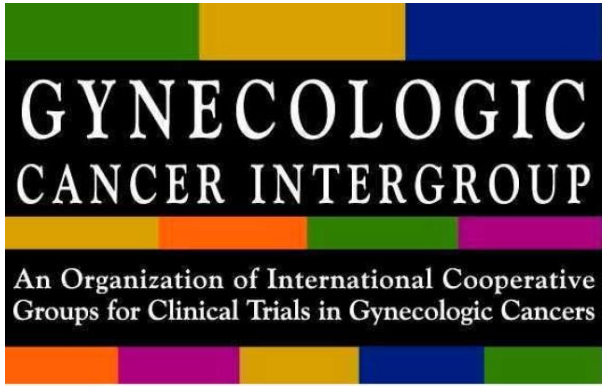

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An Organization of International Cooperative Groups for Clinical Trials in Gynecologic Cancers

ConCerv Trial

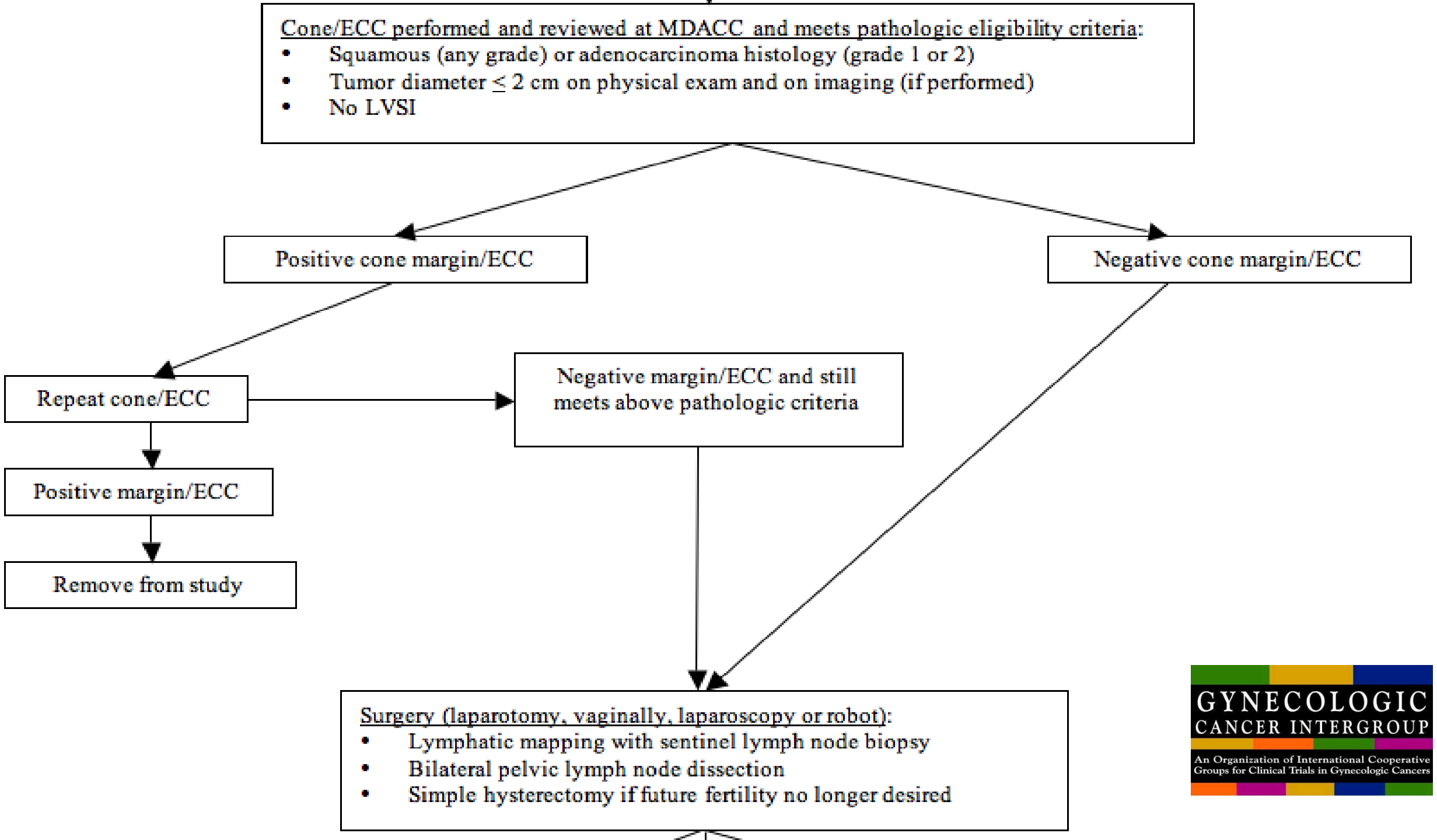
Objective:

Safety and feasibility of conservative surgery in early stage cervical cancer

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

Sample Size: 100 patients


Cone/ECC performed and reviewed at MDACC and meets pathologic eligibility criteria:
• Squamous (any grade) or adenocarcinoma histology (grade 1 or 2)
• Tumor diameter ≤ 2 cm on physical exam and on imaging (if performed)
• No LVSI
Positive cone margin/ECC
Negative cone margin/ECC
Repeat cone/ECC
Negative margin/ECC and still meets above pathologic criteria
Positive margin/ECC
Remove from study
Surgery (laparotomy, vaginally, laparoscopy or robot):
• Lymphatic mapping with sentinel lymph node biopsy
• Bilateral pelvic lymph node dissection
• Simple hysterectomy if future fertility no longer desired
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ConCerv Trial (*N=70*)

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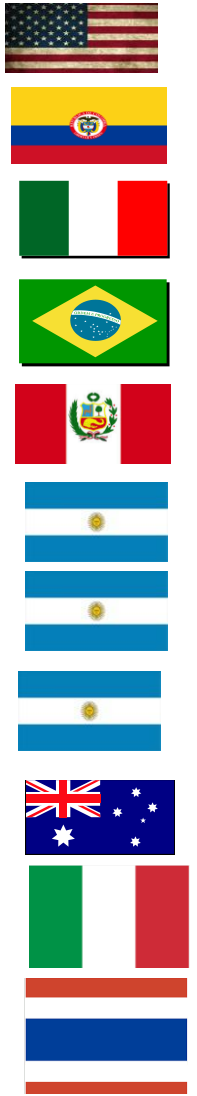
- MD Anderson, USA (K. Schmeler)
- IDC, Colombia (R. Pareja)
- INCAN, Mexico (D. Cantu)
- Barretos, Brazil (J. Humberto-Fregnani)
- INEN, Peru (A. Lopez)
- Hospital Britanico (Julian DiGuilmi)
- Instituto de Onco, Argentina (M. Riege)
- Hospital Italiano, Argentina (M. Perrotta)
- Royal Women's, Australia (O. McNally)
- Policlinico Gemeli (A. Fagotti)
- Chula University, Thailand (T. Manchana)



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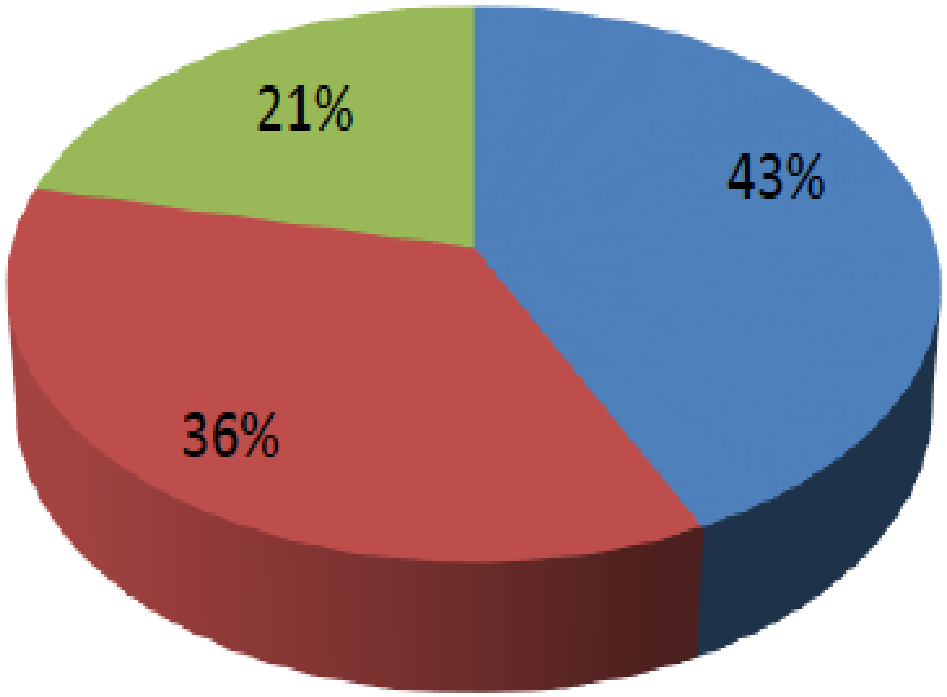
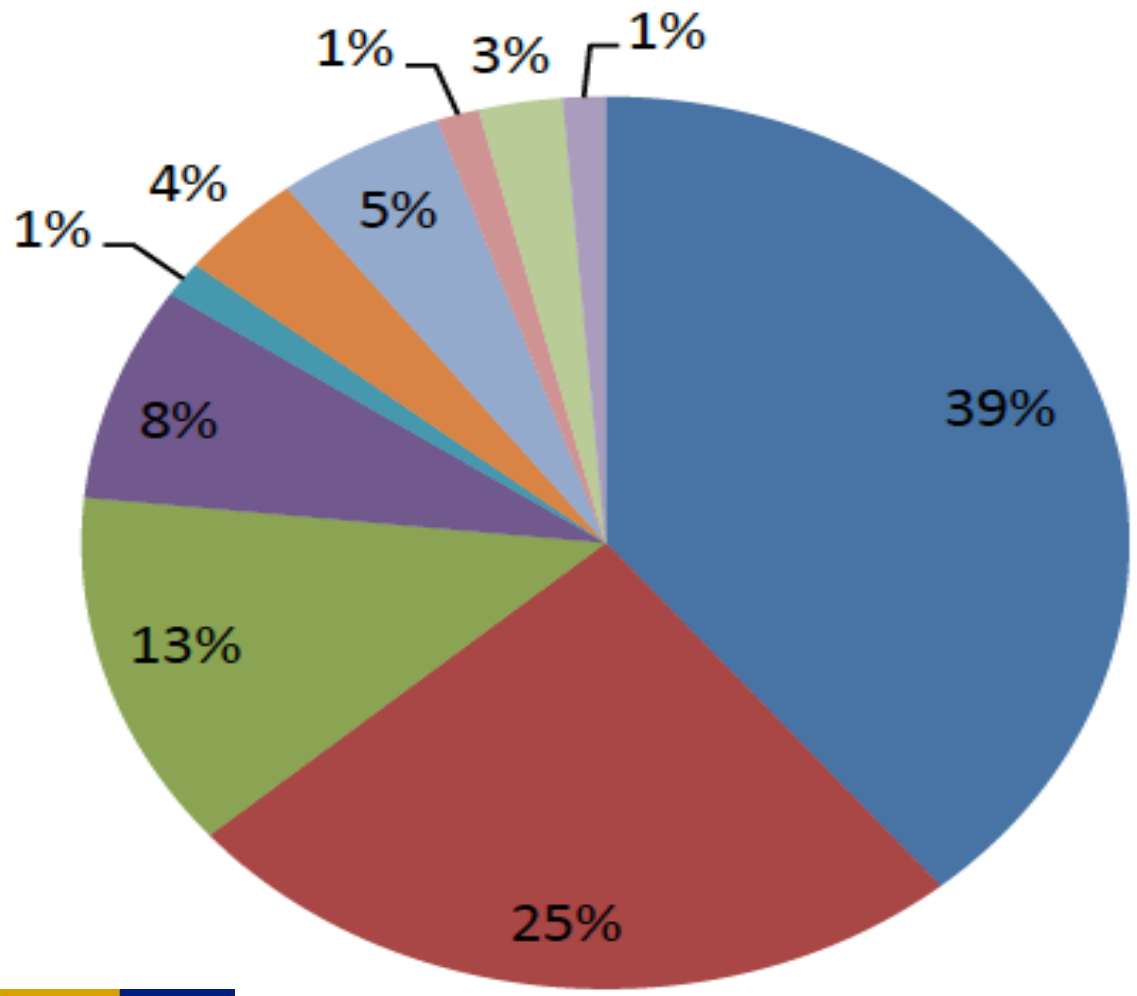
Surgery Type



- Simple Hysterectomy & Lymphadenectomy
- Cone & Lymphadenectomy
- Cut-through Hysterectomy & Lymphadenectomy

Registration by Site



- MD Anderson
- Clinica Las Americas, Medellin, Colombia
- INEN, Lima, Peru
- Hospital Italiano, Buenos Aires, Argentina
- Instituto de Oncologia, Santa Fe, Argentina
- INCAN, Mexico City
- BCH- Barretos, Brazil
- Royal Womens Victoria, Australia
- LBJ County Hospital Houston, TX
- Policlinica Gemelli Rome, Italy

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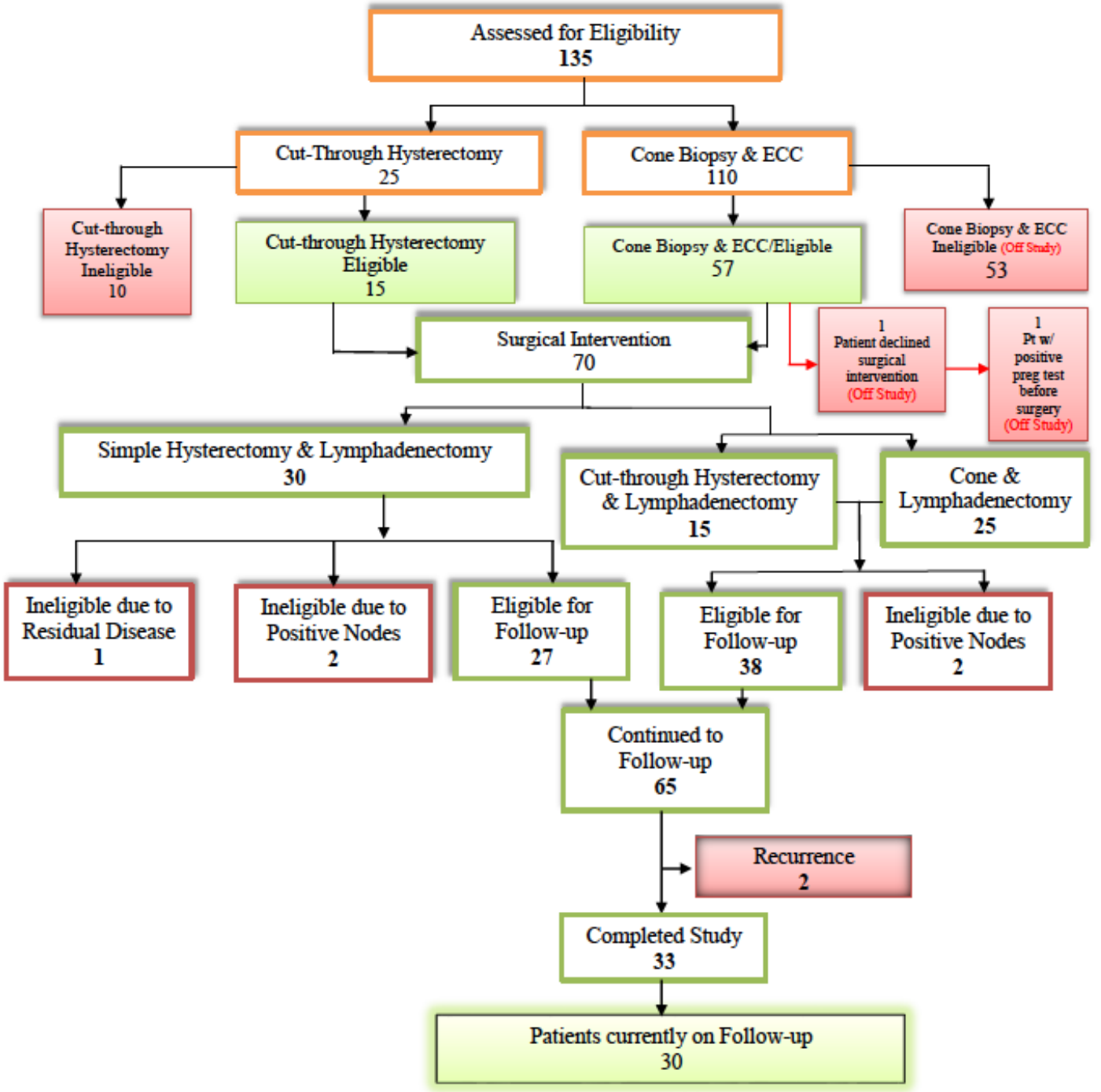
ConCerv Trial



ConCerv – Preliminary (*N=70*)

- 4 patients with positive nodes **(4.3%)**

- Two recurrences **(2.9%)**:
  - Deep stromal invasion and CIN3 at margins, inclusion criteria changed
  - Peritoneal disease <1y after conservative surgery

- One patient with residual disease at hysterectomy **(1.4%)**:
  - Multiple previous cones for AIS
  - No changes to inclusion criteria

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A Phase III Randomized Clinical Trial Comparing Laparoscopic or Robotic Radical Hysterectomy with Abdominal Radical Hysterectomy in Patients with Early Stage Cervical Cancer

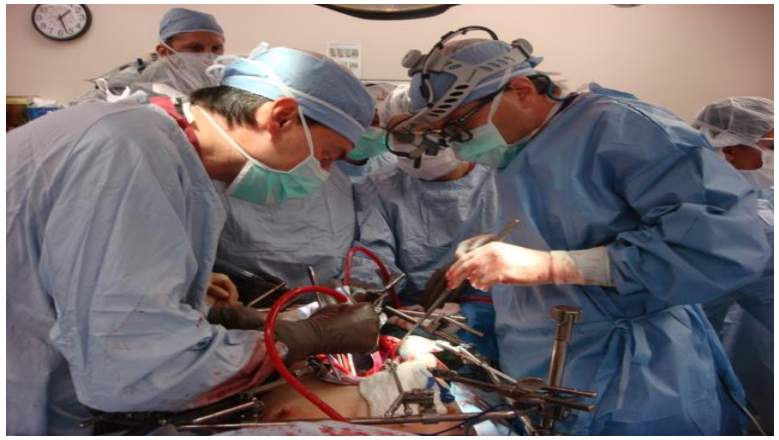
Andreas Obermair, MD*, Val Gebski, MD, Michael Frumovitz, MD, MPH, Pamela T. Soliman, MD, MPH, Kathleen M. Schmeler, MD, MPH, Charles Levenback, MD, and Pedro T. Ramirez, MD

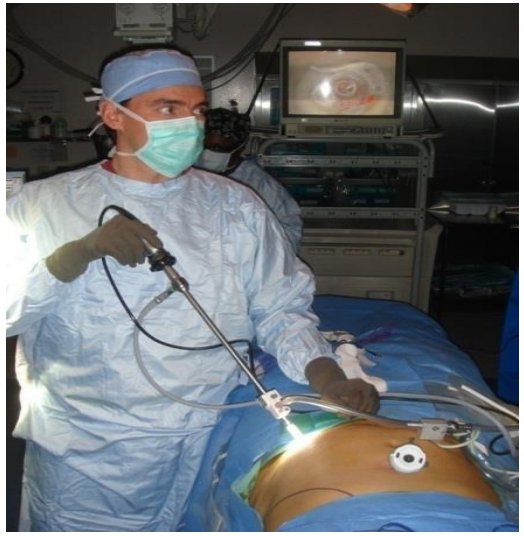
N=740

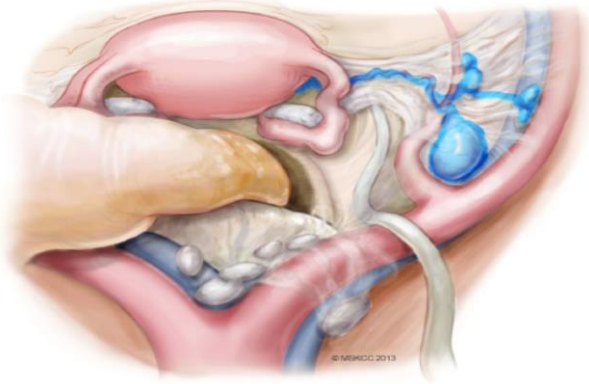
International Collaboration

End points:

- **DSF**
- **Recurrence rate**
- **Overall survival**
- **Treatment-related morbidity**
- **QOL**
- **Lymphatic mapping feasibility**







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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)
  - -FACT-Cx/MDASI/SF-12
  - -Health Services
  - -EuroQoL-5D
- Assess pelvic floor function
  - -Pelvic Floor Distress Inventory (PFDI)
- Overall survival between arms
- Feasibility of sentinel lymph node biopsy

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Inclusion Criteria

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1 Histologically confirmed primary adenocarcinoma, squamous cell carcinoma or adenosquamous carcinoma of the uterine cervix;

2 Patients with FIGO stage IA1 (with lymph vascular space invasion), IA2, or IB1 disease;

3 Patients undergoing either a Type II or III radical hysterectomy (Piver Classification)

4 Patients with adequate bone marrow, renal and hepatic function:

- 4.1 WBC > 3,000 cells/mcl
- 4.2 Platelets >100,000/mcl
- 4.3 Creatinine <2.0 mg/dL (non – IDMS)
- 4.4 Bilirubin <1.5 x normal and SGOT or SGPT <3 x normal

5 Performance status of ECOG 0-1;

6 Patient must be suitable candidates for surgery;

7 Patients who have signed an approved Informed Consent;

8 Patients with a prior malignancy allowed if > 5 years previous with no current evidence of disease;

9 Females, aged 18 years or older.

10 Negative serum pregnancy test $\leq$ 30 days of surgery in pre-menopausal women and women < 2 years after the onset of menopause

Sites Continent

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North America = 9

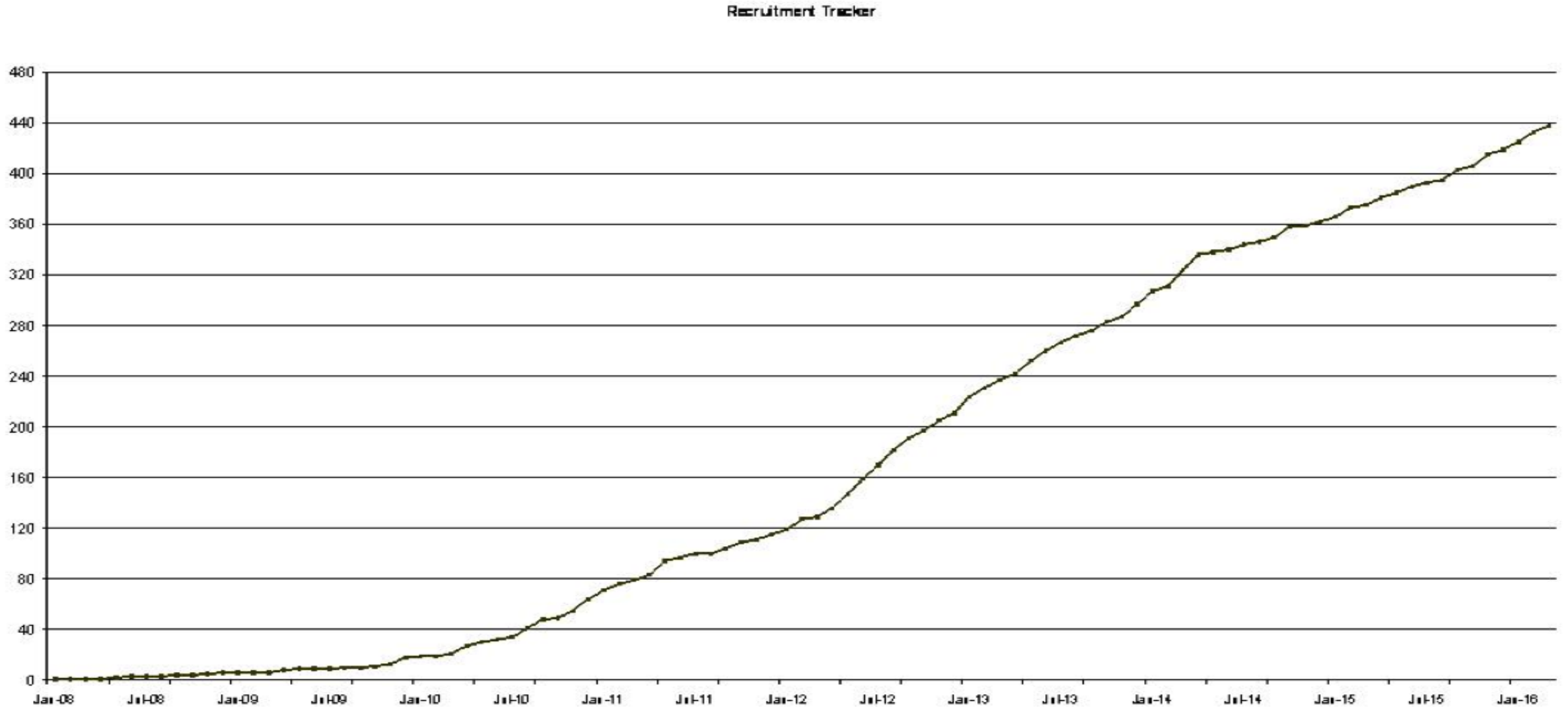
- **Canada – 1**
- **United States – 8**

South/Central America = 5

- **Brazil – 3**
- **Colombia – 1**
- **Mexico – 1**

Asia/Oceania= 13
China (3)
Korea (3)
India (1)
Australia (6)

Europe = 4
Bulgaria (1)
Italy (3)



Recruitment Tracker January 2008 - March 2016

LACC Accrual