GCIG CERVIX CANCER BRAINSTORMING DAY
Thursday, 6 November, 2014
Melbourne, Australia

Satoru Sagae (JGOG)
Bradley Monk (GOG)
1. Surgery plus Radiation +/- CT post operative radiation  

KGOG–0801/GOG263 (RTOG): RT vs CCRT in intermediate risk cervix cancer after hysterectomy  
Ryu 145–>170 /480

RTOG–0724 (GOG): ChemoRT with and without adjuvant chemotherapy in high risk cervix cancer after hysterectomy  
Small  <100? /400

NAC+surgery VS CCRT  

EORTC 55994: Randomized phase III study of NAC followed by RH vs CCRT in FIGO stage Ib2, Ila>4 cm or IIb cervical cancer  
Casado completed June 2014/625

KGOG 1029  A Randomized Controlled Trial Comparing Radical Hysterectomy plus Tailored Adjuvant Therapy versus Primary Chemoradiation Therapy in Bulky Early–stage Cervical Cancer  
Park too early/409

Paraaortic Lymphadenectomy  

G–GOC LiLACS  Lymphadenectomy in Locally Advanced Cervix Study  
Stage IB2–IVA Cervical Cancer PET (+) Pelvic Nodes/ (−) Paraaortic Nodes  
Laparoscopic Paraaortic Lymphadenectomy /Tailored ChemoXRT (Experimental) vs Whole Pelvic Chemoradiation Therapy (Standard of Care)  
Frumovitz 350?/600
Accrual of GOG 263

Golobal
EORTC 55994: Randomized phase III study of neoadjuvant chemotherapy followed by surgery vs. concomitant radiotherapy and chemotherapy in FIGO stage Ib2, IIa > 4 cm or IIb cervical cancer.

**PI’s:** G. Kenter, S. Greggi, F. Landoni

**Primary endpoint:**
- Overall survival at five years

**Secondary endpoints:**
- Overall survival
- Progression free survival
- Toxicity
- Quality of life

- **Accrual (n = 626) completed June 2014**
  - Expected study completion = mid 2019

- **Protocol amendment (v4.0):**
  - New primary end-point: OS at 5 years instead of OS
  - Secondary end-point: OS
  - Change of total number of patients: 625 (instead of 686)
  - Revised TR chapter

**Regulatory submissions amendment under preparation by EORTC HQ**
2. Chemoradiation related trials:

KGOG–Thai TACO: (RTOG, GICOM) (CCRN – Viet Nam, Thailand) Randomized Clinical Trial of Weekly versus Tri–Weekly Cisplatin based Chemoradiation in Locally Advanced Cervical cancer

Ryu 75–>130 /590

ANZGOG OUTBACK: (GOG, RTOG) (CCRN – India) :
Chemoradiotherapy +/- adjuvant chemotherapy  Mileshkin 254–>432 /780

McCormack 14 –>38 /700

RTOG: A RANDOMIZED PHASE III STUDY OF STANDARD VS. IMRT PELVIC RADIATION FOR POST–OPERATIVE TREATMENT OF ENDOMETRIAL AND CERVICAL CANCER: TIME–C
Small 100? /284

histology

JGOG1074 : A New Protocol Concept for Advanced Cervical Adenocarcinoma of the Uterine Cervix CCRT–P (RT + CDDP 40 mg/m² weekly) VS CCRT–TP (RT + CDDP 30 mg/m² + PTX 50 mg/m² weekly)
Fujiwara just started/240
A Phase III trial of adjuvant chemotherapy following chemoradiation as primary treatment for locally advanced cervical cancer compared to chemoradiation alone: THE OUTBACK TRIAL

ACCRUAL = 432 / 780

Groups involved
- NRG Oncology
- ANZGOG
- G-GOC (pending)

Countries involved
- Australia, New Zealand
- USA
- Canada
- Singapore
- Saudi Arabia
- Pending: China, Brazil, Columbia
INTERLACE

• 20 Sites now open UK- most in past 2/12
• Mexico- ethics approval pending
• IMRT amendment approved Oct 14
• Recruitment still very slow- 38 pts
  ( the larger centres suspended accrual pending IMRT amendment )
• Discussions ongoing with Italian groups
3. Minimal invasive surgery related trials:
NCIC–CTG CX 5 SHAPE: (DGOG, ) (CCRN –) A RANDOMIZED TRIAL COMPARING RADICAL HYSTERECTOMY AND PELVIC NODE DISSECTION VS SIMPLE HYSTERECTOMY AND PELVIC NODE DISSECTION IN PATIENTS WITH LOW RISK EARLY STAGE CX CA:
Plante 11–>50 /700

G–GOC ConCerv Conservative Surgery for Early Stage Cervical Cancer: Tailoring Radicality to Risk Factors CONE+PLN, SH+PLN, cut-through hyst Schmeler 38/100

G–GOC LACC A Phase III Randomized Clinical Trial of Laparoscopic or Robotic Radical Hysterectomy versus Abdominal Radical Hysterectomy in Patients with Early Stage Cervical Cancer Ramirez 355/740

GOG–0278 Conservative surgery (cone/nodes or hyst/(nodes) in early stage cervical cancer. (evaluation of physical function and QOL) Monk 9–>? /220

4. Vulvar Cancer
DGOG GROINSS–V II (EORTC, GOG) : Groningen International Study on Sentinel Nodes in Vulvar Cancer Creutzberg for van der Zee 1,037 cases
GOG–0279 Phase II Trial Evaluating Cisplatin (NSC #119875) and Gemcitabine (NSC #613327) Concurrent with Intensity–Modulated Radiation Therapy (IMRT) in Treatment of Locally Adv. SC C of the Vulva Monk 9–>? /52
<table>
<thead>
<tr>
<th>Country</th>
<th># Patients Accrued</th>
<th>GCIG Group</th>
<th>Status</th>
</tr>
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<tbody>
<tr>
<td>Canada</td>
<td>39</td>
<td>KGOG (Korea)</td>
<td>Actively accruing</td>
</tr>
<tr>
<td>South Korea</td>
<td>7</td>
<td>AGO –Austria</td>
<td>Actively accruing</td>
</tr>
<tr>
<td>Austria</td>
<td>3</td>
<td>ICORG (Ireland)</td>
<td>Actively accruing</td>
</tr>
<tr>
<td>Ireland</td>
<td>1</td>
<td>China (Fudan University)</td>
<td>Pending site activation</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>50</strong></td>
<td>NCRI - UK</td>
<td>Pending site activations</td>
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<td></td>
<td></td>
<td>BGOG (Belgium)</td>
<td>Pending site activations</td>
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<td>GINECO (France)</td>
<td>Pending contract/agreement</td>
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<td>DGOG (The Netherlands)</td>
<td>Pending contract/agreement</td>
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<td>NSGO (Nordic Countries)</td>
<td>Pending contract/agreement</td>
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<td>AGO - Germany</td>
<td>Pending funding</td>
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<td></td>
<td>G-GOC (USA, South America)</td>
<td>Will participate after completion of ConCerv</td>
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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)

* We are looking for additional collaborators
ConCerv - Results

• 78 patients enrolled

• 42 eligible after MDACC pathology review
  – 19 simple hysterectomy + nodes
  – 14 cone + nodes
  – 5 cut-through hysterectomy
  – 4 Surgery Pending
LACC Sites Continent

North America = 8
• Canada – 1
• United States – 7

South America = 5
• Brazil – 2
• Colombia – 1
• Mexico – 1
• Argentina – 1

Oceania = 5
• Australia – 5
LACC Sites Continent

ASIA = 7
- China – 3
- Korea – 3
- India - 1

Europe = 4
- Bulgaria – 1
- Italy – 3