

**A RANDOMIZED TRIAL COMPARING RADICAL
HYSTERECTOMY AND PELVIC NODE DISSECTION
VS SIMPLE HYSTERECTOMY AND PELVIC NODE
DISSECTION IN PATIENTS WITH LOW-RISK,
EARLY- STAGE CERVICAL CANCER**

A Gynecologic Cancer Intergroup (GCIg) Trial led by the NCIC CTG

GCIg Trial Designation: The **SHAPE Trial
NCIC CTG Protocol Number: **CX.5****

Chair: Marie Plante

NCIC Clinical Trials Group
NCIC Groupe des essais cliniques



Trial Schema

Low-risk cervical cancer as defined by:

- squamous cell, adenocarcinoma, adenosquamous carcinoma
- Stage **IA2** and modified **IB1**
- < 10mm SI on LEEP/cone
- < 50% stromal invasion on MRI
- max dimension of **≤ 20 mm** on MRI
- Grade 1-3 or not assessable

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ARM 1 (Control)
Radical Hysterectomy*

Arm 2 (Experimental)
Simple Hysterectomy*

→→Pelvic relapse

- * Regardless of treatment assignment, surgery will include pelvic lymph node dissection with optional sentinel lymph node (SN) mapping. If SN mapping is to be done, the mode is optional, but the laparoscopic approach is preferred.

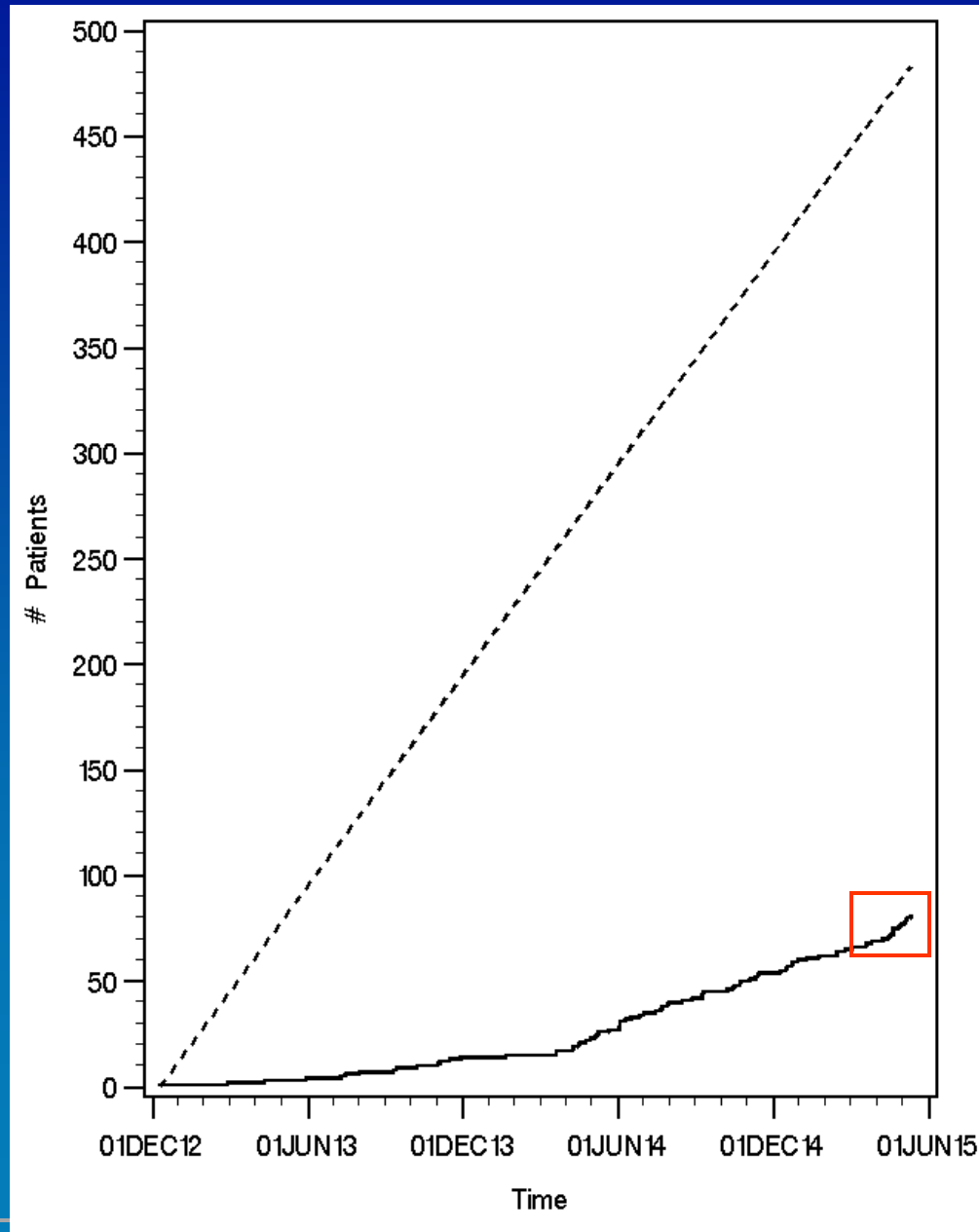
Planned sample size: **700** (non-inferiority at 0.05 level with 80% power)

Current Status

Country	# Sites Activated
Canada	17
South Korea	1
Austria	7
Ireland	1
The Netherlands	1
Belgium	11
China	1
Total	39

Country	# Patients Accrued
Canada	60
South Korea	7
Austria	4
Ireland	4
The Netherlands	4
Belgium	1
China	1
Total	81

Current Status



Current Status

GCIIG Group	Status
UK	1 st Patient June 2015
France (32 sites)	1 st Patient June 2015
Germany	Needs funding

Patient Characteristics

	Radical Hyst N=34	Simple Hyst N=35	Total N=69
Age (median)	43	40	42
Intended SLN mapping			
yes	17 (50%)	18 (51%)	35 (51%)
no	17 (50%)	17 (49%)	34 (49%)
FIGO Stage			
IA2	2 (6%)	4 (11%)	6 (9%)
IB1	32 (94%)	31 (89%)	63 (91%)
Histology			
Squamous	21 (62%)	22 (63%)	43 (62%)
Adenocarcinoma	13 (38%%)	13 (37%)	26 (38%)

Patients who received Adjuvant Treatment

	Radical Hyst N=31	Simple Hyst N=30	Total N=61
Adjuvant Treatment	5 (16%)	2 (6.7%)	7 (11.5%)

Reason for Adjuvant Therapy	Radical Hyst N=31	Simple Hyst N=30	Total N=61
Non-SLN mets	2 (6.5%)	0	2 (3.3%)
SLN mets	2 (6.5%)	1 (3.3%)	3 (4.9%)
Extrauterine disease	2 (6.5%)	0	2 (3.3%)

Summary

- We have reached **10%** of total accrual
- We look forward to the contribution of **France** and **UK**
- Once stabilized, we may be looking at non-GCIG centers (CCRN initiative)
 - South America, Moscow etc