



**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 (GCIIG) Trial led by the CCTG

GCIIG Trial Designation: The **SHAPE Trial
CCTG Protocol Number: **CX.5****

Chair: Marie Plante

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.

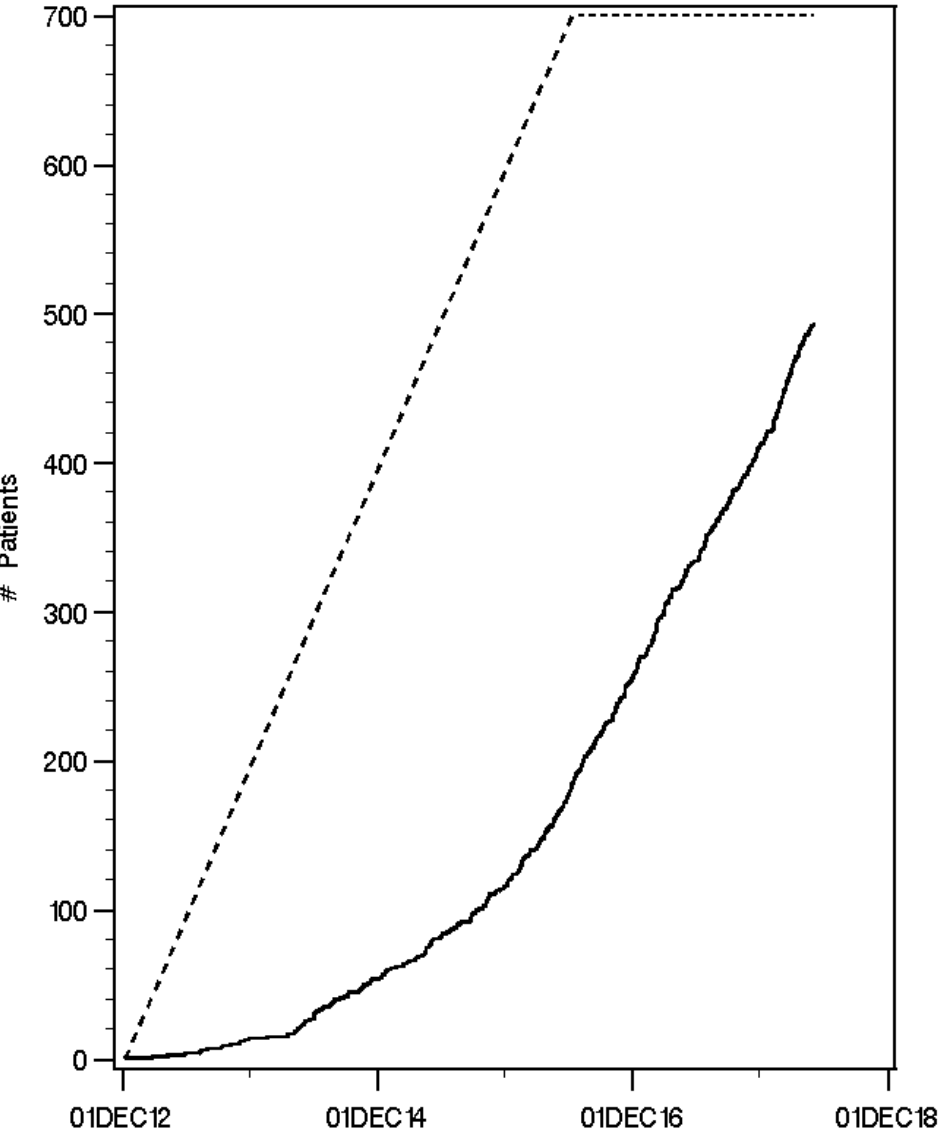
Planned sample size: **700** (non-inferiority at 0.05 level with 80% power)

Current Status

Country	# Sites Activated
Canada	15
France	33
The Netherlands	7
UK	25
Belgium	10
Austria	7
Germany	16
Ireland	1
South Korea	3
Norway	1
Russia	1
China	1
Total	120

Country	# Patients Accrued
Canada	152
France	95
The Netherlands	78
UK	71
Belgium	31
Austria	23
Germany	15
Ireland	11
South Korea	14
Norway	7
Russia	2
China	2
Total	501

Current Status



- We have reached **71.5%** of total accrual
- We hope to be able to activate two CCRN sites in Brazil in Q3 of 2018.
- It is our current estimation that accrual will continue until Q3 2019.