# SHAPE - (dernière mise à jour : 05/08/2019)

ARCHIMAIDindex.php?action=show&id=103

## Informations générales

**Titre de l'étude** : Essai randomisé de phase III comparant une hystérectomie élargie avec lymphadénectomie pelvienne à une hystérectomie simple avec lymphadénectomie pelvienne chez des patientes atteintes de cancer débutant du col utérin à bas risque

**Traitement** : Chirurgie

**Type d'étude** : Hors ciblage moléculaire

**Phase** : III **Stade** : Localisé **Ligne(s)** :

**Schéma** : A Randomized Phase III Trial Comparing Radical Hysterectomy and Pelvic Node Dissection vs Simple Hysterectomy and Pelvic Node Dissection in Patients With Low-Risk Early Stage Cervical Cancer (SHAPE)

2 arms:
- Active Comparator: Radical Hysterectomy
This procedure may be performed abdominally, laparoscopically, robotically or vaginally. The uterus, cervix, medial 1/3 of parametria, 2cm of the uterosacral ligaments and upper 1-2cm of the vagina are to be removed en bloc. The uterine artery is ligated laterally to the ureters and the ureters are unroofed to the ureterovesical junction.
- Experimental: Simple Hysterectomy
This procedure may be performed abdominally, laparoscopically, robotically or vaginally. Extrafascial hysterectomy involves removal of the uterus with cervix without adjacent parametria. The uterine arteries are transected medial to the ureters at the level of the isthmus and the uterosacral ligaments are transected at the level of the cervix. Surgeons should pay special attention to make sure that the whole cervix is removed. As such, a maximum of 0.5 cm of vaginal cuff can be removed to ensure the complete removal of the cervix.

## Spécialités / Localisations

**Spécialité n°1** : Seins, organes génitaux de la femme

**CIM10 - Localisation n°1** : **C53** - Tumeur maligne du col de l'utérus

## Critères

**Critères d'inclusion** : - Histologically confirmed adenocarcinoma, squamous, or adenosquamous cancer of the cervix. Diagnosis has been made by LEEP, cone or cervical biopsy and has been reviewed and confirmed by the local reference gynecological pathologist.

- Patient has been classified as low-risk early-stage cervical cancer. These patients include:
• FIGO Stage IA2 [FIGO Annual Report, 2009], defined as:
o evidence of disease by microscopy;
-> for patients who underwent a LEEP or cone:
- histologic evidence of depth of stromal invasion > 3.0 and <= 5.0 mm based on the local reference pathologist's measurement of the LEEP or cone specimen;
- histologic evidence of lateral extension that is <= 7.0 mm based on the local reference pathologist's measurement of the LEEP or cone specimen; and

negative margins (patients with positive margins are considered IB1, see below)
-> for patients who underwent a cervical biopsy only:
- radiologic evidence of less than 50% stromal invasion based on pelvic MRI
• FIGO Stage IB1 [FIGO Annual Report, 2009] with favorable (low risk) features, defined as:
o measured stromal invasion and lateral extension that meet the criteria for IA2 (see above) but with positive margins;
o evidence of disease by clinical exam; lesion must clinically measure <= 20 mm
o evidence of disease by microscopy;
-> for patients who underwent a LEEP or cone:
- histologic evidence of depth of stromal invasion between 5.1-10 mm and/or lateral extension between 7.1-20.0 mm based on the local reference pathologist's measurement of the LEEP or cone specimen
-> for patients who underwent a cervical biopsy only:
- radiologic evidence of less than 50% stromal invasion based on pelvic MRI
- lateral extension <= 20 mm based on clinical exam or radiologic imaging.
In addition to above criteria on maximal stromal invasion of <= 10 mm, the lesion must be no larger than 20 mm in any dimension by any assessment method (MRI, clinical or histological exam). To ensure patients meet this criterion, investigators may need to sum the lesion measurements from biopsy and other methods that evaluate it in the same plane.
Patients are eligible irrespective of the presence or absence of lymph-vascular space involvement (LVSI).

- Physical examination, recto-vaginal examination and visualization of the cervix by speculum or colposcopic examination have been done after the initial diagnostic procedure (LEEP, cone or biopsy) and prior to randomization.

- Chest x-ray or CT scan of chest AND pelvic MRI* done after initial diagnostic procedure (LEEP, cone or biopsy) and prior to randomization.
The CT should be a 16 slice (or higher) helical scanner. Oral and intravenous contrasts are preferred (unless there is a contraindication to the use of contrast) with scan obtained in the portal phase at a slice thickness of 5mm or lower Pelvic MRI should be performed on a 1.5 or 3 Tesla magnet with pelvic phased-array coils. The MR pulse sequences will consist of T1 gradient echo in the axial plane at 5 mm slice thickness and fast spin echo in the axial, sagittal, and coronal planes at 4 mm slice thickness. The short axis (perpendicular to the tumour's long axis) with a 3 mm slice thickness is required in the best plane to show the maximum thickness of stromal invasion. Use of an anti-peristaltic agent is mandatory while intravenous use of gadolinium or diffusion-weighted imaging (DWI) is optional.
* Note: pelvic MRI is optional if the patient has stage IA2 disease and underwent a LEEP or cone.

- After consideration of a patient's medical history, physical examination and laboratory testing, patients must be suitable candidates for surgery as defined by the attending physician / investigator.

- Patients must have no desire to preserve fertility.

- Patients fluent in English or French must be willing to complete the Quality of Life Questionnaire. The baseline assessments must be completed within 6 weeks prior to randomization. Inability (illiteracy in English or French, loss of sight, or other equivalent reason) to complete the questionnaires will not make the patient ineligible for the study. However, ability but unwillingness to complete the questionnaires will make the patient ineligible. As additional GCIG groups join the study, more translations of some of the questionnaires may be added.
Patients fluent in English or French who reside in Canada and the United Kingdom must agree to participate in the economic evaluation component of this trial and complete the Health Economics Questionnaire. Similarly, patients fluent in English or French accrued from other GCIG groups who are participating in the economic evaluation must be willing to complete the Health Economics Questionnaires.

- Patient consent must be appropriately obtained in accordance with applicable local and regulatory requirements. Each patient must sign a consent form prior to enrolment in the trial to document their willingness to participate.

- Patients must be accessible for treatment and follow-up. Investigators must assure themselves the patients randomized on this trial will be available for complete documentation of the treatment, adverse events, and follow-up.

- Surgery is to be done within 20 weeks of initial diagnosis (NO EXCEPTIONS). The 20-week period includes time required for diagnosis, referral, diagnostic staging, randomization and scheduling of the surgical procedure.

- Patients must be >= 18 years old.

**Critères de non-inclusion** : - Patients with FIGO 1A1 disease [FIGO Annual Report, 2009].

- History of other malignancies, except: adequately treated non-melanoma skin cancer, curatively treated in-situ cancer of the

cervix, or other solid tumours, Hodgkin's lymphoma or non-Hodgkin's lymphoma curatively treated with no evidence of disease for > 5 years.

- Patients with evidence of lymph node metastasis on preoperative imaging or histology.

- Patients who have had or will receive neoadjuvant chemotherapy.

- Patients who are pregnant.

## Informations promoteur

**Nom du promoteur** : Institut Claudius Regaud

**Type de promoteur** : Institutionnel

**Adresse** : - 31100 TOULOUSE

**Coordonnateur** : - *Mail :* - *Tél :*

## Informations centre investigateur n°1

**Nom du centre** : Centre François BACLESSE

**Adresse** : 3 avenue du Général Harris 14000 CAEN

**Investigateur** : Florence JOLY

**TEC / ARC / IDE** : Jérémy BOUTROIS - *Mail :* j.boutrois@baclesse.unicancer.fr - *Tél :*

**Ouverture de l'essai** : OUVERT

## Liens utiles

**ClinicalTrials** : https://clinicaltrials.gov/ct2/show/NCT01658930?titles=shape&cntry1=EU%3AFR&rank=5