ARCOL - (dernière mise à jour : 08/01/2020)

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Informations générales

Titre de l'étude : Etude de phase II de radiothérapie adaptative dans le traitement des cancers localement avancés du col utérin

Traitement : Néoadjuvant / Radiothérapie

Type d'étude : Hors ciblage moléculaire

Phase : II **Stade** : NA **Ligne(s)** :

Schéma :
This study evaluates the effect of adaptative Intensity-Modulated Radiation Therapy (IMRT) in the treatment of locally advanced cervical cancer on acute genito-urinary (GU), and gastrointestinal (GI) toxicities. Every patients will be treated according to the adaptative IMRT strategy.

Study arm - Experimental: Adaptative Treatment plans
A Library of treatment plans will be generated for each patient before starting radiochemotherapy (standard treatment). This Library will be created using CT-Scans with variable bladder filling (and hence different uterine positions). Each day of radiotherapy treatment, an appropriate plan is chosen based on Imaging that day.

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 : - Cervix carcinoma proved by histology
- According International Federation of Gynecology and Obstetrics (FIGO) classification, stages IB2, IIA, IIB, IIIA and IIIB without lumbo-aortic lymph node damage (surgical or radiologic)
- Patient treated with radio-chemotherapy then curietherapy with curative aim, validated in multidisciplinary meeting
- Renal, hepatic and cardiovascular functions that allow administration of the associated systemic treatment
- Older than 18 years
- Good general status, World Health Organization less or equal to 1
- Signed informed consent

Critères de non-inclusion : - History of cancer that is not controlled and / or treated for less than 5 years (excepted for cutaneous baso-cellular cancer)
- History of pelvic irradiation
- Simultaneous participation to another research that could interfere with the study results
- Pregnant or breastfeeding patient
- Patient under tutor or guardian
- Patient not able to respect medical follow-up for geographical, social or psychological reasons
- Not affiliated to a system of French social security

Informations promoteur

Nom du promoteur : CENTRE EUGÈNE MARQUIS

Type de promoteur : Institutionnel

Adresse : - 35000 RENNES

Coordonnateur : - *Mail :* - *Tél :*

Informations centre investigateur n°1

Nom du centre : Centre Oscar Lambret

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Investigateur : Docteur Xavier MIRABEL

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Ouverture de l'essai : CLOS

Liens utiles

ClinicalTrials : https://clinicaltrials.gov/ct2/show/NCT02937948