CGFL CENTRE GEORGES FRANÇOIS LECLERC Ensemble, dépassons le cancer	**CRITERES DE SELECTION** **ETUDE ETOILE**	Identité patient (coller étiquette patient)
Version 1.0 du 30/11/2021	Investigateur en charge du patient : …….. PI : **Dr Gilles TRUC** Mail : gtruc@cgfl.fr *A contacter pour adresser/inclure patient externe au CGFL*	Arc : **Philippe BATAILLARD** Poste :8137

« ETOILE »

Randomized trial comparing hadrontherapy by carbon ions versus conventional radiotherapy – including protontherapy – for the treatment of radioresistant tumors

Arm
Experimental: Carbon ions therapy Radical and exclusive carbon ions radiotherapy
Active Comparator: Conventional radiotherapy Radical radiotherapy by Xrays and / or protons

Intervention/treatment
Radiation: Carbon ions therapy External radiotherapy by accelerated carbon nucleus in a specialized hadrontherapy center
Radiation: Advanced external radiotherapy by Xrays or protons Radiotherapy by any appropriate advance procedure of photontherapy (IMRT, Volumetric Modulated Arc Therapy (VMAT), Tomo, etc.) or when possible by protontherapy or even a combination of both types of radiotherapy

VALIDATION DES CRITERES DE SELECTION

Critères d'inclusion :

Age ≥ 18 years	□ oui □ non
Absence of severe comorbidities and life expectancy > 10 years	□ oui □ non

CGFL CENTRE GEORGES FRANÇOIS LECLERC Ensemble, dépassons le cancer	**CRITERES DE SELECTION** **ETUDE ETOILE**	Identité patient (coller étiquette patient)
Version 1.0 du 30/11/2021	Investigateur en charge du patient : …….. PI : **Dr Gilles TRUC** Mail : gtruc@cgfl.fr *A contacter pour adresser/inclure patient externe au CGFL*	Arc : **Philippe BATAILLARD** Poste :8137

Unresecable or inoperable cancer or macroscopically incomplete resection (R2)	□ oui □ non
Eligible radioresistant cancers: ***If several items are ticked "yes", patient cannot be selected*** ***If all the items are ticked "No", patient cannot be selected*** Head or neck adenoid cystic carcinoma (laryngeal and tracheal localisations excluded) a. Soft tissue sarcoma b. Pleomorphic rhabdomyosarcoma only (alveolar and embryonal forms excluded) c. Retroperitoneal sarcoma under condition of technical feasibility (movement) d. Osteosarcoma of any grade and localisation (Ewing sarcoma excluded) e. Chondrosarcoma (excluding skull base) OMS grade > 2 f. Chordoma: axial skeleton or pelvis (excluding skull base) g. Angiosarcoma .	□ oui □ non
Absence of epidermal invasion (a hypodermic invasion is accepted with fixity of cutaneous plan but no true epidermal permeation)	□ oui □ non
Performance Status (PS) ECOG □ 2 or Karnofsky scale ≥ 60% **and patient able physically and psychologically to accept and undergo care abroad (Pavia in Italy)**	□ oui □ non
For women of childbearing age, absence of pregnancy or use of a reliable contraception method	□ oui □ non
Patient beneficiary of Social Insurance	□ oui □ non
Informed signed consent	□ oui □ non
Validation of radiotherapy indication by the local RCP	□ oui □ non

<u>Critères de non inclusion :</u>

.

Complete macroscopic or microscopic surgical resection (R0 or R1)	□ oui □ non
Previous radiotherapy in the volume to be treated	□ oui □ non
Metastatic disease	□ oui □ non

CGFL CENTRE GEORGES FRANÇOIS LECLERC Ensemble, dépassons le cancer	**CRITERES DE SELECTION** **ETUDE ETOILE**	Identité patient (coller étiquette patient)
Version 1.0 du 30/11/2021	Investigateur en charge du patient : …….. PI : **Dr Gilles TRUC** Mail : gtruc@cgfl.fr *A contacter pour adresser/inclure patient externe au CGFL*	Arc : **Philippe BATAILLARD** Poste :8137

Contraindication for performing a radiotherapy by photons, protons or carbon ions (impossibility to stand / support in decubitus position, to maintain or support the immobility or the immobilization required for the treatment, a situation of acute uncompensated physiological failure, the presence of an infection in the target volume of the irradiation in one of the compulsory beam entrance of the treatment, absence of enough space between an organ at risk and the target volume, except the possibility of a "spacer" insertion)	□ oui □ non
Planned surgery or chemotherapy after the radiotherapy	□ oui □ non
Presence in the target volume of metallic material which cannot be removed (carbon fibres material authorised)	□ oui □ non
History or presence of concomitant cancer, except in-situ cervical uterine cancer or cured basocellular cutaneous carcinoma, or any cured cancer with no sign of relapse during the last 5 years	□ oui □ non
Pregnancy or woman of childbearing age not accepting to undergo a reliable contraception method	□ oui □ non
Simultaneous participation to another prospective clinical trial	□ oui □ non
Impossible follow-up over 5 years	□ oui □ non

Date : _____

Signature de l'investigateur : _____