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

PHRC ETOILE

CASE REPORT FORM

SPONSOR			
Hospices Civils de Lyon	3 Quai des Célestins BP 2251 69229 Lyon cedex 02	annie.iung@chu-lyon.fr	04.72.40.68.24
PRINCIPAL INVESTIGATOR			
Pascal Pommier	Radiothérapie Centre Léon Bérard 28 rue Laënnec 69373 Lyon Cedex 08	pascal.pommier@lyon.unicancer.fr	04.78.78.51.66
ASSOCIATE INVESTIGATOR			
Jacques Balosso	Service de radiothérapie CHU de Grenoble ; BP217 38043 Grenoble Cedex 09	JBalosso@chu-grenoble.fr	04.76.76.54.35
STUDY COORDINATION			
Abdoul Kader SOUMAI	Faculté de médecine Laennec Service de Pharmacologie Clinique et Essais Thérapeutiques 7-11 rue Guillaume Paradin 69008 – Lyon	abdoul-kader.soumai-alloh@chu-lyon.fr	04.78.78.57.78

PATIENT'S IDENTIFICATION

Centre: |___|___|

Patient n° : |___|___|___|

Initials : |___|___|___|
(2 letters: 1st letter of last name – 1st letter of first name)
(3 letters in case of composite last name or first name)

Randomisation date : |___|___|___|___|___|___|

Inclusion form

To be filled in by French investigator after the local RCP approval and prior to randomisation

Centre: |__|__| **Patient: |__|__|__|** **Initials: |__|__|__|**

Date of consent signature: |__|__|__|__|__|__|__|__|

1. Inclusion criteria

1.1	Age ≥ 18 years	Yes ☐	No ☐
1.2	Absence of severe comorbidities and life expectancy > 10 years	Yes ☐	No ☐
1.3	Unresecable or inoperable cancer or macroscopically incomplete resection (R2)	Yes ☐	No ☐
1.4	Eligible radioresistant cancers:		
	If several items are ticked "yes", patient cannot be selected		
	If all the items are ticked "No", patient cannot be selected		
	1.4.1 Head or neck adenoid cystic carcinoma (laryngeal and tracheal localisations excluded)	Yes ☐	No ☐
	1.4.2 Soft tissue sarcoma	Yes ☐	No ☐
	1.4.3 Pleomorphic rhabdomyosarcoma only (alveolar and embryonal forms excluded)	Yes ☐	No ☐
	1.4.4 Retroperitoneal sarcoma under condition of technical feasibility (movement)	Yes ☐	No ☐
	1.4.5 Osteosarcoma of any grade and localisation (Ewing sarcoma excluded)	Yes ☐	No ☐
	1.4.6 Chondrosarcoma (excluding skull base) OMS grade ≥ 2	Yes ☐	No ☐
	1.4.7 Chordoma: axial skeleton or pelvis (excluding skull base)	Yes ☐	No ☐
	1.4.8 Angiosarcoma	Yes ☐	No ☐
1.5	Absence of epidermal invasion (a hypodermic invasion is accepted with fixity of cutaneous plan but no true epidermal permeation)	Yes ☐	No ☐
1.6	Performance Status (PS) ECOG ≤ 2 or Karnofsky scale ≥ 60% **and patient able physically and psychologically to accept and undergo care abroad (Pavia in Italy)**	Yes ☐	No ☐
1.7	For women of childbearing age, absence of pregnancy or use of a reliable contraception method	Yes ☐	No ☐
1.8	Patient beneficiary of Social Insurance	Yes ☐	No ☐
1.9	Informed signed consent	Yes ☐	No ☐
1.10	Validation of radiotherapy indication by the local RCP	Yes ☐	No ☐

If at least one item ticked "No" (except in 1.4 item), patient cannot be selected

2. Non-inclusion criteria

2.1	Complete macroscopic or microscopic surgical resection (R0 or R1) ..	Yes ☐	No ☐
2.2	Previous radiotherapy in the volume to be treated.....	Yes ☐	No ☐
2.3	Metastatic disease.....	Yes ☐	No ☐
2.4	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).....	Yes ☐	No ☐
2.5	Planned surgery or chemotherapy after the radiotherapy	Yes ☐	No ☐
2.6	Presence in the target volume of metallic material which cannot be removed (carbon fibres material authorised)	Yes ☐	No ☐
2.7	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.....	Yes ☐	No ☐
2.8	Pregnancy or woman of childbearing age not accepting to undergo a reliable contraception method	Yes ☐	No ☐
2.9	Simultaneous participation to another prospective clinical trial	Yes ☐	No ☐
2.10	Impossible follow-up over 5 years	Yes ☐	No ☐

If at least one item ticked "Yes", patient cannot be selected.

Message to be displayed at the end of this form:

- **This patient is eligible (all inclusion criteria present, all non-inclusion absent).**
- **Patient is not eligible (at least one inclusion criterion ticked "no" and/or at least one non-inclusion criterion ticked "yes")**