

Gilles DULUC

Directeur de la Recherche Clinique
et de l'Innovation

Talence, le 13/05/2025

Jeanne PATARD

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Département Promotion Interne

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Object : Interventional Clinical Trial's results posting to the European Clinical Trial register (EudraCT) of the European Medicines Agency (EMA).

In accordance of Directive 2001/20/CE

Study Title : MISORL : Pronostic Evaluation of 18FMISO PET-CT in Head and Neck Cancer

EudraCT Nbr : 2008-006411-20

Sponsor Nbr : CHUBX2008/20 / **Afssaps Nbr :** A81186-28

Transitioned study to the Regulation (EU) 536/2014 : no

Status of the study : Study prematurely ended

The recruitment rate of patients has been under the target (16 patients included out of the 50 planned) resulted in impossibility to meet the main objective of the prognostic value of [¹⁸F]-FMISO imaging in the study group. The study has given information to determine the best segmentation method for obtaining hypoxic volumes.

The best image contrast is obtained after 4 hours of acquisition (*publication : Henriques de Figueiredo B, Merlin T, de Clermont H, Hatt M, Visvikis D, Vimont D, Fernandez P, Lamare F. (2013) : Potential Use of [¹⁸F]-Fluoromisonidazole Positron Emission Tomography for Radiotherapy Planning in Head and Neck Squamous Cell Carcinomas Strahlentherapie und Onkologie, 189(12), 1015-1019*).

Based on the hypoxic biological volumes predefined by the FLAB method, a dose escalation simulation was proposed, assessing the impact on target organs such as the salivary glands (*publication : Henriques de Figueiredo B, Zacharatou C, Galland-Girodet S, Benech J, De Clermont-Gallerande H, Lamare F, Hatt M, Digue L, De Mones del Pujol E, Fernandez P.*

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(2015) Hypoxia imaging with [18F]-FMISO-PET for guided dose escalation with intensity-modulated radiotherapy in head-and-neck cancers. *Strahlentherapie und Onkologie*, 191(3), 217-224).

For the Head of the University Hospital of Bordeaux
and by delegation,
The Director of the Clinical research and Innovation

Gilles DULUC

par délégation, Jeanne Pakard, directrice adjointe



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