CRP E33035

CRP on Resource Sparing Curative Radiotherapy for Locally Advanced Squamous Cell Cancer of the Head and Neck (the HYPNO trial)

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Summary:

Worldwide, head and neck squamous cell carcinomas (HNSCC) comprise approximately 7% of all incident cancers, and of these 64% are seen in low and middle income countries. Life-style factors, in particular tobacco and alcohol consumption, are major etiological factors, although an increasing number of HNSCC cases are associated with viral infections (Epstein Barr Virus and Human Papillomavirus). Radiation therapy (RT) alone or combined with cytotoxic or molecular targeted agents is a mainstream definitive treatment for previously untreated locally advanced disease. This therapy offers organ and functional preservation in many cases with an approximate 30-50% of cases obtaining long-term loco-regional tumour control.

Accelerated RT, that is increasing the dose above the standard 10 Gy per week, has been shown in a large number of randomized controlled trials to be associated with an improved efficacy/toxicity ratio relative to standard fractionation, provided a careful balance between total dose, dose per fraction and overall treatment time is chosen. The attractive feature of this approach is that the total treatment time is shorter than the conventional treatment (4 vs. 7 weeks in this case), thus being convenient for the patient, and the department can increase 75% the number of treated patients with the same workload.

By optimizing fractionation of radiotherapy in a resource sparing combined modality approach, it is expected that Member States will benefit from the rational use of existing equipment and staff levels, decreasing costs, yet providing optimal treatment for patients. This CRP continues Agency's research efforts which have improved the clinical practice in radiotherapy of locally advanced HNSCC cancer.

Overall Objective:

To improve policies in MS concerning radiotherapy and cancer treatment for HNSCC, and ensuring effective and efficient utilization of current and future advanced cancer radiotherapy treatment technologies.

Specific Research Objectives:

The objectives of the proposed CRP are

- To run a clinical trial to test a resource sparing fractionation regime to treat HNSCC (66 Gy given in 33 fractions (6 fractions per week) vs. 55 Gy given in 20 fractions (5 fractions per week), and

The clinical objective is to demonstrate that radiotherapy for HNSCC can be safely delivered in 4 weeks with results similar to DAHANCA in terms of local control and late toxicity. DAHANCA has already proved to be superior to conventional fractionation.

The study design is a stratified, balanced, and randomized study (phase III) of patients with Stage I-IV squamous cell carcinoma of the pharynx (except nasopharynx), larynx (except stage I-II glottic carcinoma) and oral cavity.

Expected Research Outputs:

New data on the efficacy of hypofractionation as a potential resource sparing approach to treat HNSCC patients;

Expected Research Outcomes:

Optimised strategy for the treatment of HNSCC in LMI countries;

Participating institutions:

Country	*City*	*Institution*	*Investigators*
Argentina	Mendoza	Fundación Escuela de Medicina Nuclear (FUESMEN)	Sergio Binia
Brasil	Barretos, Sao Paulo	Hospital do Cancer de Barretos	Alexandre Jacinto
Cuba	La Habana	Instituto Nacional de Oncología y Radiobiología (INOR)	Misleidy Nápoles
India	Mumbai	Advanced Centre for Treatment Research & Education in Cancer (ACTREC) - Tata Memorial Centre	Tejpal Gupta, Jai Prakash Agarwal (JP)
India	New Delhi	Department of Radiation Oncology, Institute Rotary Cancer Hospital (IRCH), All India Institute of Medical Sciences (AIIMS)	Bidhu K. Mohanti
Indonesia	Jakarta	Dr. Cipto Mangunkusumo National General Hospital, University of Indonesia	Nana Supriana, Soehartati Gondhowiardjo (Tati)
Pakistan	Bahawalpur	Bahawalpur Institute of Nuclear Medicine and Oncology (BINO)	Jabeen Kaukab
Philippines	Quezon	St. Luke's Medical Center	Miriam Calaguas
South Africa	Johannesburg	Department of Radiation Oncology, University of the Witwatersrand	Roy Lakier
Thailand	Bangkok	Department of Radiology, Siriraj Hospital, Faculty of Medicine, Mahidol University	Yaowalak Chansilpa, Kullathorn Thephamongkol
TFYR of Macedonia	Skopje	Radiotherapy and Oncology University Clinic	Valentina Krstevska, Igor Stojkovski
Uruguay	Montevideo	Instituto de Radiología y Centro de Lucha Contra el Cáncer (IRCLCC), Centro Hospitalario Pereira Rossell (HPR)	Sergio Aguiar

USA	Madison	University of Wisconsin, Madison	Søren Bentzen, Rick Chappell