

## **CRP E33030**

### ***Altered Fractionation and Radio-Sensitisation in Head and Neck Cancer Radiotherapy***

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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.

By optimizing fractionation of radiotherapy and evaluating the role of radiosensitizer 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 enhance MS capabilities to establish sound policies concerning radiotherapy and cancer treatment, and ensuring effective and efficient utilization of current and future advanced cancer radiotherapy treatment technologies.

#### ***Specific Research Objectives:***

A CRP is proposed to study the impact of radiosensitizer in the radiotherapy treatment of squamous cell head and neck cancer. The aim of the study is to determine the possible therapeutic gain of using nimorazole given as a hypoxic radiosensitizer in conjunction with accelerated fractionated radiotherapy in invasive squamous cell carcinoma of the larynx, pharynx and oral cavity, and evaluate the tolerance, compliance and toxicity of using nimorazole.

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 and stage I-II glottic carcinoma), larynx and oral cavity.

The study randomizes to accelerated radiotherapy (6 fractions per week 66/Gy in 32 F in 5.5 weeks) with or without the hypoxic radiosensitizer Nimorazole, and the stratification is based on the following parameters: Tumour stage: T1-2, T3-4, Nodal stage: No vs. N1-3, tumour localization: pharynx, larynx, oral cavity, institution.

#### ***Expected Research Outputs:***

- New data on efficacy of radiosensitizing drug on loco regional tumour control and survival of HNSCC patients
- Improved treatment practice for patients with locally advanced HNSCC

- PhD project expected to be included for translational research conducted in the study coordinator center.

### **Expected Research Outcomes:**

It is expected that the study will demonstrate

- Improvement in locoregional control and disease specific survival of HNSCC when radio sensitizer is added to radiotherapy
- Guidelines and improved strategy for treatment of HNSCC for the LMI countries
- Technology transfer and increased capacity building in training activities through translational research component within the PhD project

### **Participating institutions:**

<i>Country</i>	<i>City</i>	<i>Institution</i>
PAKSITAN	KARACHI	Pakistan Atomic Energy Commission (PAEC); Karachi Nuclear Power Plant (KANUPP); Atomic Energy Medical Centre
PAKISTAN	PESHAWAR	Pakistan Atomic Energy Commission (PAEC); Institute of Radiotherapy and Nuclear Medicine (IRNUM)
SLOVENIA	LJUBLJANA	Institute of Oncology; Department of Radiation Oncology
EGYPT	CAIRO	Cairo University; National Cancer Institute (NCI)
INDIA	CHANDIGARH	Postgraduate Institute of Medical Education and Research (PGIMER); Department of Radiotherapy
INDIA	MUMBAI	Tata Memorial Centre
POLAND	GLIWICE	Maria Sklodowska-Curie Memorial Cancer Center and Institute of Oncology
ESTONIA	TALLINN	Estonian Radiation Protection Centre (EKK); North Estonia Medical Center; Cancer Centre; Radiotherapy Departmen
PAKISTAN	ISLAMABAD	Nuclear Medicine, Oncology & Radiotherapy Institute; Radiation Oncology Departmen
DENMARK	AARHUS	Aarhus University Hospital; Department of Experimental Clinical Oncology