

CRP E33034

Resource-Sparing Curative Treatment for Rectal Cancer

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Summary:

The use of a shortened fractionation schedule in the neoadjuvant (preoperative) treatment of rectal cancer has been popular in Europe since its introduction by a Swedish group in 1990.

This form of treatment is given in one week, thus providing convenience for the patients and resource-sparing for the treatment centres and has been widely tested in a number of European studies in resectable rectal cancer and more recently in unresectable rectal cancer as well, yielding encouraging results. However, this hypofractionated schedule has not been adopted in developing countries yet.

This CRP attempts to compare the short fractionation to a standard fractionation plus chemotherapy (the control arm) with the double aim of turning unresectable patients resectable (and thus increasing their chances of operability and cure) as well as make the participating centres familiar with this schedule and adopt it in their routine practice.

Therefore this is a prospective randomized phase III clinical trial comparing a short fractionation schedule of 25 Gy in 5 fractions over one week, to 50 Gy in 25 fractions over 5 weeks combined with chemotherapy as pre-operative treatment for locally advanced, unresectable rectal cancer. The use of pre-operative chemotherapy in the short fractionation arm of the study will be decided during the First Coordination Meeting.

Overall Objective:

To establish the resectability rate of two different fractionation schedules in the preoperative treatment of unresectable rectal cancer.

Specific Research Objectives:

- Determine the resectability rate for two different preoperative regimens
- Determine the local control rate in resected patients
- Determine the overall survival rate in resected patients
- Determine the early toxicity rate of two fractionation schedules
- Determine the pre-operative mortality rate in resected patients

Expected Research Outputs:

- Determination of the relative value of two fractionation regimens in terms of their resectability rate in unresectable or borderline resectable rectal cancer.
- Patients initially diagnosed with unresectable rectal cancer, are turned resectable by radiotherapy, thus increasing their chances of survival and cure.

Expected Research Outcomes:

- Participating centres become familiar with the use of a short hypofractionation radiotherapy regimen in the pre-operative treatment of rectal cancer.

- Radiotherapy centres in Member States increase the use of hypo fractionated radiotherapy regimes which are convenient for patients and resource sparing for centres and strained health budgets.

Participating institutions:

<i>Country</i>	<i>City</i>	<i>Institution</i>
Algeria	Blida	Hôpital Frantz Fanon; Centre Anti-Cancer Cité des Anvassers
Brazil	Sao Paulo	Fundacao "Antonio Prudente"; Hospital "A.C. Camargo"
PR. of China	Beijing	Chinese Academy of Medical Sciences
Colombia	Bogotá	Ministerio de Salud; Instituto Nacional de Cancerología
Croatia	Zagreb	University Hospital "Sestre Milosrdnice"; Department of Oncology and Nuclear Medicine
Cuba	La Habana	Instituto Nacional de Oncología y Radiobiología (INOR)
India	Mumbai	Tata Memorial Centre
India	Coimbatore	GKNM Hospital; V.N. Cancer Center; Department of Radiation Oncology
Indonesia	Jakarta	University of Indonesia; Faculty of Medicine; Dr. Cipto Mangunkusumo National General Hospital; Department of Radiotherapy
Italia	Roma	Universita Cattolica del Sacro Cuore; Istituto di Radiologia; Divisione di Radioterapia Oncologica
Slovakia	Bratislava	National Cancer Institute
Canada	Mississauga	Credit Valley Hospital (data management)