Sponsor:	Istituto di Ricerche Farmacologiche Mario Negri IRCCS - Via G. La Masa 19, 20156 Milano
Study Title:	"Intergroup Trial in Adjuvant Chemotherapy for Adenocarcinoma of the Stomach): comparison of the efficacy of a peri-operative versus a post-operative chemotherapy treatment in patients with operable gastric cancer and assessment of the benefit of a post-operative chemo-radiotherapy"
Short Title:	-
Acronym:	ITACA-S 2
EudraCT:	2010-021052-25
Phase:	III
Start Date (mm/dd/yyy):	11/05/2010
Completion date (mm/dd/yyy):	12/31/2013
Reason for interruption:	Poor enrollment
Keywords:	peri vs post operative chemoterapy; radiotherapy; gastric cancer

Short Report

ITACA-S 2 was planned with a 2x2 factorial design, thus consisting of two independent studies, following specific eligibility criteria and with different randomization scheme: the Timing Study and the RTX Study. Both studies were Italian, multicentre, open-label, randomized, superiority, phase III trials conducted in patients with histologically confirmed, localized gastric adenocarcinoma, which was considered operable. In the Timing Study patients were randomized with a 1:1 ratio to receive: peri-operative (Arm A) or post-operative (Arm B) chemotherapy (CHT).

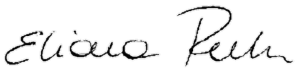
Once randomized in the Timing Study, patients may also be randomized in the RTX Study to receive in addition to CHT a post-operative radiotherapy (RTX) treatment or no other treatment. This was possible since the randomization was done in two steps: the first for the Timing Study for all the participating centres (peri-operative CHT vs. post-operative CHT) and the second one for the RTX Study, only for centres with the radiotherapist willing and able to participate (post- surgical CHT-RTX vs. no other treatment). Thus the following four arms were generated: peri-operative CHT (Arm A); post-operative CHT (Arm B); peri-operative CHT + post-operative CHT-RTX (Arm C); post-operative CHT + post-operative CHT-RTX (Arm D).

Based on case-mix of sample 1000-1180 patients were needed in the Timing study and 420-520 in the RTX study.

The study addressed two primary questions, according to its factorial design: to compare the efficacy in terms of overall survival of a peri-operative vs. a post-operative CHT treatment, irrespectively of the presence of a post-surgical CHT-RTX (Timing Study); to compare the efficacy in terms of one year relapse free survival of a post-surgical CHT-RTX treatment vs. no other treatment, irrespectively of the timing of CHT (RTX Study).

The trial has been prematurely closed on 31 December 2013. This decision was taken due to unsatisfactory recruitment by the fifty-five participating experimental centers, despite all the numerous attempts on our part to reverse this trend.

At that date only 61 patients were enrolled, 16 in the timing study only, and 45 in the radiotherapy study, about 2% and 9% respectively of the expected sample (1000-1180 in the Timing Study and 420-520 in the Radiotherapy Study). The formal communication of premature closure of the study was sent to the National Competent Authority (Italian Medicines Agency, AIFA) and to all Ethics Committees of the participating centres through a letter dated 15 March 2014.



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