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J-POUCH vs STRAIGHT
Randomized Multicentre Clinical Trial

Colonic J-pouch reconstruction versus straight colorectal anastomosis after low anterior resection for rectal cancer: impact on anastomotic leak, bowel function and quality of life

Introduction

On 26th October 2009, the clinical trial *"Colonic J-pouch reconstruction versus straight colorectal anastomosis after low-anterior resection for rectal cancer: impact on anastomotic leak, bowel function and quality of life"*, coordinated by the Clinica Chirurgica II, University Hospital of Padua, randomized the first patient after obtaining Ethical Committee approval on 21st September 2009.

This study is a multi centre clinical trial sponsored by renowned scientific societies such as the Italian Society of Colorectal Surgery (SICCR) and the Italian Society of Oncologic Surgery (SICO). The protocol is already active in several clinical centres, such as: the "Fondazione Pascale" National Cancer Institute of Naples, the University Hospital of Padua, the "S. Orsola-Malpighi" University Hospital of Bologna, the Oncology Institute of Vojvodina (Serbia), the National Cancer Institute of Aviano, the Hospital of Sanremo, the "Umberto I" University Hospital of Rome, the National Cancer Institute of Rionero in Vulture, the "Garibaldi-Nesima" Hospital of Catania, the Monserrato Hospital of Cagliari, the "Carlo Poma" Hospital of Mantova.

Other centres are currently awaiting approval from their Ethical Committees.

The J-POUCH VS STRAIGHT trial aims to assess whether the incidence of major anastomotic leaks, following low-anterior resection for rectal cancer, is reduced by using the J-pouch reconstruction technique as opposed to straight colorectal anastomosis. Only patients with low and middle rectal cancer, that undergo total mesorectal excision by either laparostomy or laparotomy, a mechanical colorectal anastomosis and either a temporary ileostomy or colostomy, will be included.

The proposed design requires an accrual of 600 patients. Two formal interim analyses will be performed after the enrolment of 1/3 and 2/3 of the total sample size, in order to early terminate the trial if the percentage of major anastomotic leaks in the J-pouch reconstruction arm is lower with respect to straight anastomosis reconstruction.

Secondary objectives are: global anastomotic leak rate (major and minor), anastomotic leak complication rate (including also anastomotic stricture and bleeding), global complication rate, general complication rate, bowel function by means of the MSKCC questionnaire score, sexual function using the "Female Sexual Function Index (FSFI)" and "International Index of erectile function (IIEF)" questionnaire scores, and the quality of life through the EORTC QLQ C-30 and CR-38 questionnaire scores.

Participation in the ancillary study, dealing with bowel function, sexual function and quality of life, will involve only those centres that are able to manage the distribution and collection of the questionnaires with a qualified and dedicated staff.

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How to participate in the study

In order to enrol patients, it is essential you have written approval from your human research ethics committee. Once this has been obtained, a copy should be sent to the Clinical Trials and Biostatistics Unit, Istituto Oncologico Veneto of Padua, together with a copy of the commitment statement (attached to the study protocol) either by fax: 0039 049 8215706 or e-mail: clinical.trial@ioveneto.it

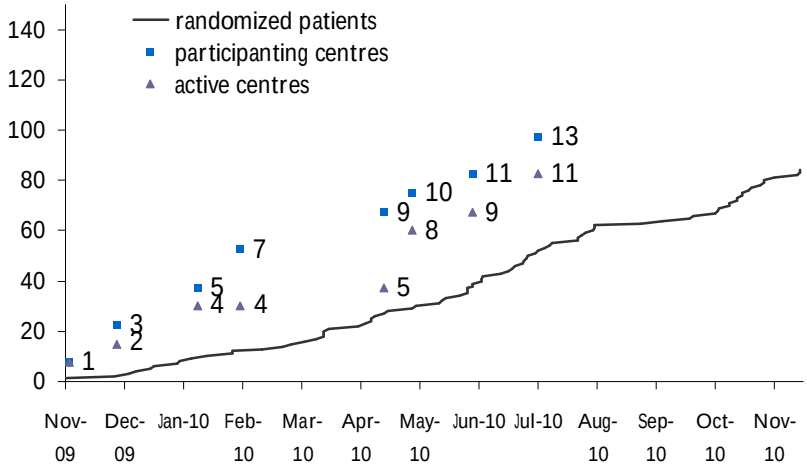
Subsequently, your centre will be authorised to randomise patients and details of how to do so will be sent by email.

Progress of the study

As of 30th November 2010, 89 patients have entered the study. The distribution of patients, randomized at each participating centre, and the date of first enrolment, can be found in the table below. Approximately 90% (80/89) of patients also compiled the quality of life and bowel function questionnaires.

Participating centres	Date 1st enrolment	N° patients enrolled
Clinica Chirurgia II, University Hospital of Padua	26/10/09	**9**
"Fondazione Pascale" National Cancer Institute of Naples	10/12/09	**32**
Patologia Speciale Chirurgica, University Hospital of Padua	05/01/10	**1**
Oncology Institute of Vojvodina, Serbia	16/01/10	**11**
"S. Orsola-Malpighi" University Hospital of Bologna	14/04/10	**2**
Colonproctologia, Hospital of Sanremo	03/05/10	**4**
Chirurgia d'urgenza retto, "Umberto I" University Hospital of Rome	17/5/2010	**3**
National Cancer Institute of Rionero in Vulture	20/5/2010	**7**
Chirurgia Oncologica, "Garibaldi-Nesima" Hospital of Catania	7/6/2010	**7**
Chirurgia Generale Oncologica, National Cancer Institute of Aviano	6/7/2010	**2**
Chirurgia Generale, Hospital of Cagliari	9/7/2010	**11**
Total		**89**

Enrolment is proceeding quit well considering that half of the participating centres obtained ethical approval less than 6 months ago.
The number of patients that each centre estimates to enrol is sufficient to guarantee the feasibility of the trial and at present only 2 centres have not yet randomized any patients.



NCI's PDQ Cancer Clinical Trials Registry

The trial has been registered with the National Cancer Institute's PDQ Cancer Clinical Trials Registry and in the National Library of Medicine's Clinical Trials.gov web site as 'NCT01110798'. The trial can be viewed on the NCI website by clicking on the link: http://www.cancer.gov/clinicaltrials/USP-1935P

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Randomization centre: Clinical Trials and Biostatistics Unit—Istituto Oncologico Veneto, Padua
- Head: Dr. Gian Luca De Salvo
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