

Titolo:	COLT colo-rectal cancer with liver transplantation: a prospective parallel trial (COLT trial)
Patologia:	Metastasi Epatiche da Tumore del Colon
Tipo di Studio:	Prospettico Multicentrico Non Randomizzato Sperimentale
Fase:	II
Principali criteri di inclusione:	• Age ≥ 18 and ≤ 69 years. • Histologically confirmed non-mucinous colon adenocarcinoma. • Pathological classification of primary tumor as pT1-3, pN0 or pN1 (metastases in < 4 regional lymph nodes), without peritoneal tumor deposits, absence of mucinous component $> 50\%$, confirmed R0 resection. No signs of extra hepatic metastatic disease or local recurrence according to CT scan+MRI+PET/CT scans. • <i>RAS</i> and <i>BRAF</i> wild-type & MSS molecular status as per local testing. • Liver metastases not eligible for curative liver resection (see “criteria for non-resectability” below) • Objective response according to RECIST 1.1 to first-line treatment, with sustained response for at least 4 months, OR disease control (CR+PR+SD) during second-line treatment for at least 4 months. • A maximum of two prior chemotherapy treatment lines. • Performance status, ECOG 0. • Satisfactory blood tests Hb $> 10\text{g/dl}$, neutrophils > 1.0 (after any G-CSF), TRC > 75, Bilirubin $< 2 \times$ upper normal level, AST, ALT $< 5 \times$ upper normal level, creatinine $< 1.25 \times$ upper normal level. • CEA $< 50 \text{ ng/ml}$ • ☐ Signed informed consent and expected cooperation of the patients for the treatment and follow-up obtained and documented according to GCP, and national/local regulations.
Principali criteri di esclusione:	• Hereditary CRC syndromes including FAP and Lynch syndrome. • Prior extra hepatic metastatic disease or primary tumor local relapse.

	• Extra-peritoneal cancers (rectum). • Palliative resection of primary CRC tumor. • Other malignancies in the previous 5 years (with exception of in situ cervical carcinoma, basal cell carcinoma, superficial bladder tumors are allowed if curatively treated). • Active intra-venous or alcohol abusers (patients may be eligible if abstention > 6 months is demonstrated) • HIV infection • Psychiatric disorders and patient low compliance • Any reason why, in the judgment of the investigators, the patient should not participate (to be formally declared)
Sede e contatti	AOU Città della Salute e della Scienza di Torino S.C. Chirurgia Generale 2U Centro Trapianto di Fegato Direttore: Prof. R.Romagnoli