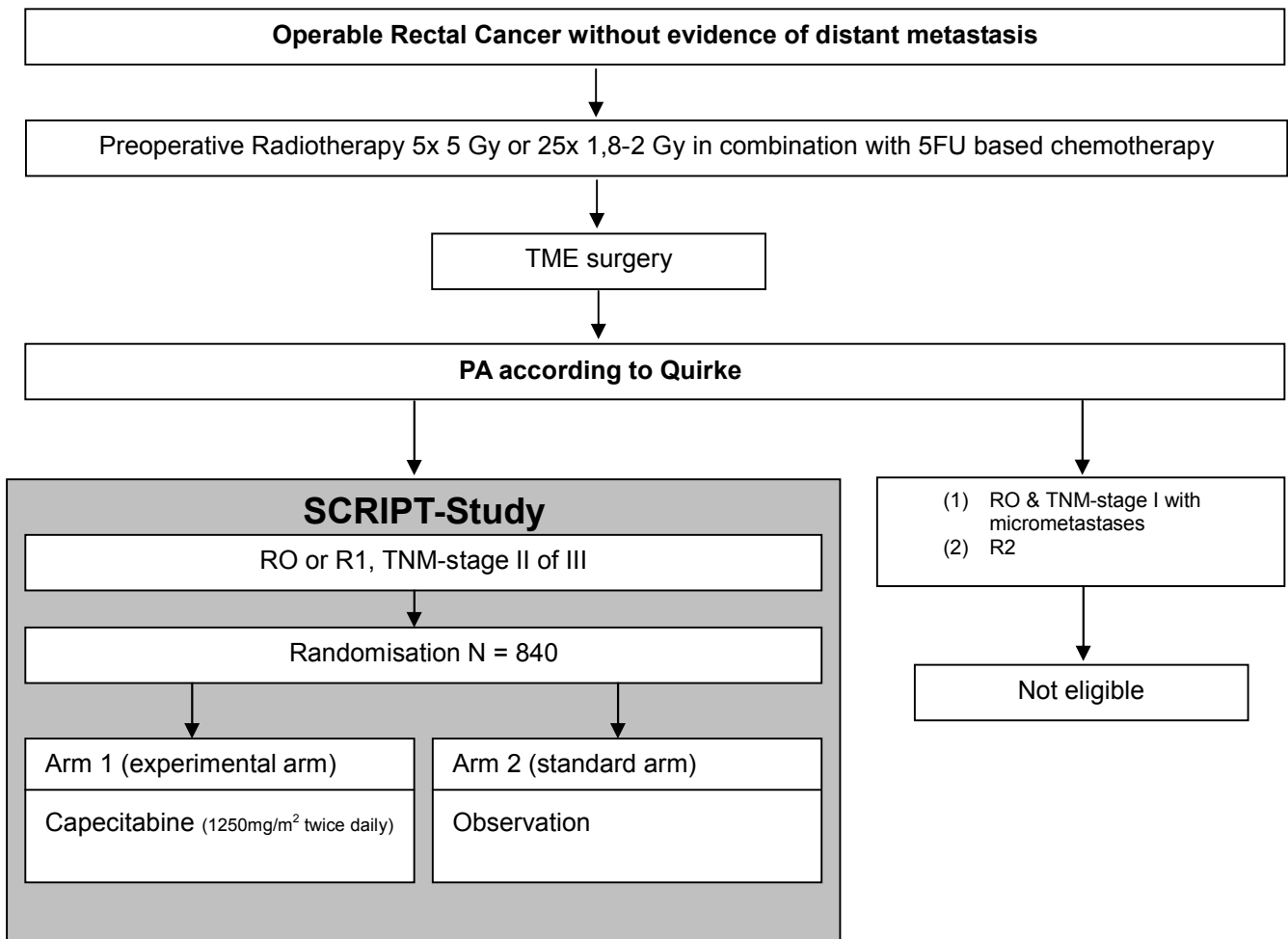


# STUDY DESIGN CKTO 2003-16 (SCRIPT)

- **SCRIPT** = **S**imply **C**apecitabine in **R**ectal cancer after **I**rradiation **P**lus **T**ME surgery
- **F**ase III study

## Design:



## **In- and Exclusion criteria:**

1. TNM stage II (T3-T4, N0) or III (any T, N+) rectal adenocarcinoma (below the level of S1/S2 or inf. margin within 15 cm of the anal verge). Patients with T1-T2, micrometastases only are excluded.
2. 5 x 5 Gy preoperative radiotherapy or preoperative chemoradiotherapy.
3. No evidence of macroscopic residual disease (R2).
4. TME surgery performed.
5. No contraindications to chemotherapy: adequate blood counts and patient is mentally and physically fit for chemotherapy according to a medical oncologist.
6. Start of chemotherapy is possible within 6 weeks after surgery.
7. WHO performance score  $\leq 2$  (0 = normal activity, 1 = symptoms, but ambulatory, 2 = in bed <50% of time).
8. Accessible for follow-up for the duration of the trial.
9. Age  $\geq 18$  years.
10. No Familial Adenomatosis Polyposis coli (FAP) or Hereditary Non-Polyposis Colorectal Cancer (HNPCC) or active Crohn's disease or active ulcerative colitis.
11. No concomitant malignancies except for adequately treated carcinoma in situ of uterine cervix or basal squamous cell carcinoma of the skin. Subjects with prior malignancies must be disease-free for at least 10 years.
12. No known Dihydropyrimidine Dehydrogenase Deficiency (DPD).
13. Written informed consent.
14. Patient is willing to complete EORTC quality of life questionnaires C30 + CR38.

Randomisation, Datacenter Heelkunde, Leiden: ☎ 071-5263500