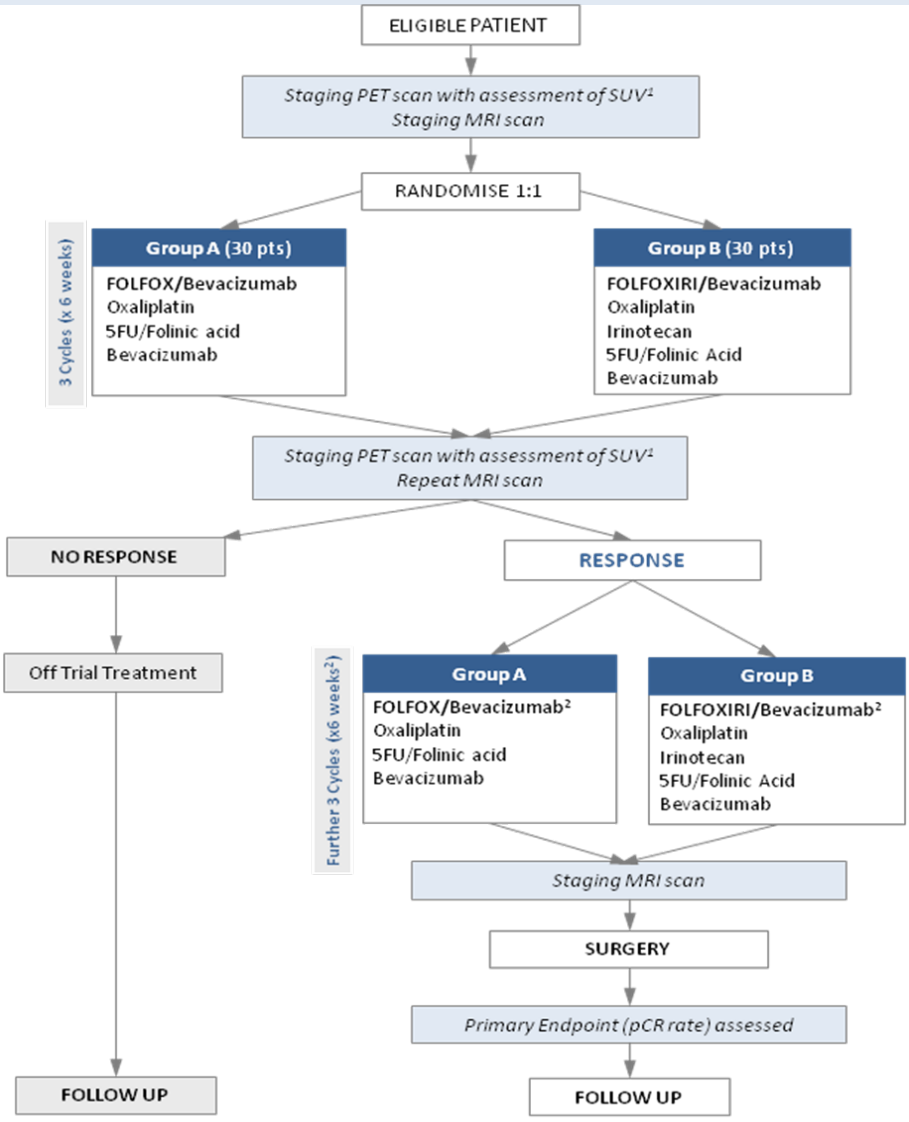
# BACCHUS

## Bevacizumab And Combination Chemotherapy in rectal cancer Until Surgery

**A Phase II, Multicentre, Open-label, Randomised Study of Neoadjuvant Chemotherapy and Bevacizumab in Patients with MRI defined High-Risk Cancer of the Rectum**

## Trial Schema




¹SUV=standardised uptake value
²Bevacizumab is omitted from the final cycle of treatment

## Endpoints

**Primary Endpoint:** Pathological complete response

**Secondary Endpoints**

- RECIST response rate
- CRM negative (>1mm) resection rate
- T and N stage downstaging
- Progression free survival
- Disease free survival
- Overall survival
- 1 year colostomy rate
- Local control (for patients that achieve a CRM negative resection)
- Frequency and severity of adverse events
- Compliance of chemotherapy treatment
- Tumour regression grade
- Tumour cell density

## Trial Overview

- **Target:** 60 patients with histologically confirmed primary rectal adenocarcinoma
- **No. of sites:** approximately 10 – 15
- **Duration of recruitment:** 18 months
- **Length of follow up:** 3 years after end of treatment

## Inclusion Criteria

- Histologically confirmed rectal cancer
- MRI evaluated locally advanced tumour:
  - T3b, T3c or T3d, N0–N2
  - OR presence of macroscopic extramural venous invasion (V2 disease)
  - **AND** T3 tumour ≥ 2mm from the mesorectal fascia
- WHO performance status 0–1
- Adequate bone marrow, hepatic and renal function
- INR ≤1.1, Urine protein <2g
- No evidence of ischemic heart disease on ECG (normal cardiovascular assessment)
- No known significant impairment of intestinal absorption

## Exclusion Criteria

- History of interstitial lung disease
- Evidence of bleeding problems or coagulopathy
- Significant and continuing rectal bleeding
- Patients receiving warfarin/coumarin derived anticoagulants
- Serious wound, ulcer or bone fracture
- History of previous malignancy in the past 5 years
- Chronic use of aspirin (>325mg/day) or clopidrogel (>75mg/day) within 10 days of start of planned trial treatment
- Serious uncontrolled intercurrent illness (including poorly controlled diabetes mellitus)
- Current or impending rectal obstruction
- Metallic colonic or rectal stent in situ
- Previous pelvic radiotherapy


**For further information, please contact:**

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