



OPERA

(Organ Preservation for Early Rectal Adenocarcinoma)

Arthur Sun Myint

Clatterbridge Cancer Centre, Liverpool, UK

Sell Your Study (OPERA)

- **Aim:**

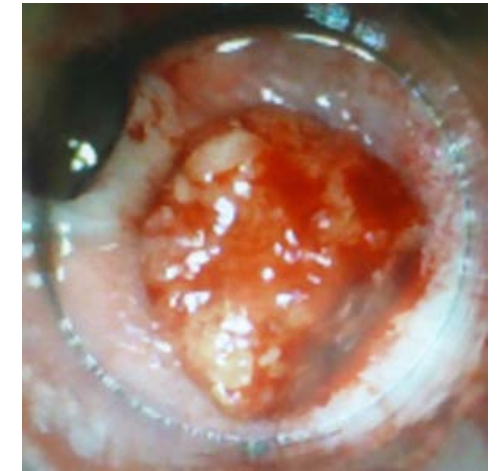
Two arm study designed to evaluate the efficacy of a CXB boost versus an EBRT boost after EBCRT.

- **Design:** Open-label,

Phase III, prospective, multi-centre, European,
Randomised 1:1,

- **Patients:** *Rectal adenocarcinoma*

*cT2/ cT3a and cT3b – cN0/ cN1 with lymph nodes <8mm
<5cm in size*



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Overview of the study

Randomisation between two arms:

- **Arm A:** 3D conformal EBCRT 45 Gy (1.8Gy/fraction/5 weeks) with concurrent chemotherapy using capecitabine (825 mg/m² bid, on radiation days).
A cone down EBRT targeting the GTV to boost primary 9 Gy in 5 fractions.
- **Arm B:** divided in 2 subgroups depending on the tumour diameter:
 - B1:** If the tumour is < 3 cm, a CXB boost dose (90Gy/3 fractions/4 weeks) will be initially delivered to the tumour. Within 2 following weeks, patients will receive 3D conformal EBRT 45 Gy (1.8 Gy/fraction/5 weeks) with
 - B2:** If the tumour is ≥ 3 cm, patients will receive EBRT first 45 Gy /25#/5 weeks

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- *Primary endpoint:*

The rate of organ(rectum) preservation either with local excision or watch and wait strategy after neoadjuvant treatment without non salvageable locally progressive disease at 3 years post treatment, or permanent stoma.

- *Secondary endpoints:*

Efficacy criteria:

- Complete Clinical Response (cCR)
- Overall survival
- Disease free survival
- Tumour regression score on the operative specimen (R0, ypT0, ypN)
- Rate of sphincter preservation

Safety criteria: Toxicity, bowel function, QLQ-C30 and QLQ-CR29 questionnaires

- *Participating centers: 3 centres (France), 4 centres (UK), 1 Sweden, 2 Switzerland, 1 Netherlands*

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- *Number pts needed:*

236 patients (118 patients/arm) must be enrolled to show a 50% increase in the main endpoint at 3 years (from 20% to 40%) H.R-0.56

- *Number pts included:* 53(France)

2 (UK)

- *Seeking for: (extra centers)-Interested centres please contact :-*

- *Contact information:*

Prof Jean Pierre Gerard (Centre Antoine Lacassagne, Nice)

Prof Arthur Sun Myint (Clatterbridge Cancer Centre, UK)

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