

# Neoadjuvant chemotherapy with S-1 and cisplatin followed by D2 gastrectomy with para-aortic lymph node dissection for gastric cancer with extensive lymph node metastasis

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## Inclusion criteria

Histologically proven gastric adenocarcinoma

Type 0, 1, 2, 3 or 5

**Bulky N2** ( $\geq 3$  cm, or at least two adjacent tumours  $\geq 1.5$  cm) and/or PAN ( $\geq 1$  cm) metastases

PAN and/or bulky N2 metastases confirmed by contrast-enhanced CT  
No distant metastasis (M0) except for PAN confirmed by contrast-enhanced CT

No more than 3 cm invasion to oesophagus

Peritoneal lavage cytology-negative for cancer cells by staging laparoscopy

Aged 20–75 years

ECOG performance status 0 or 1

No history of chemotherapy and radiotherapy for any cancer, and surgery for stomach

No previous surgery for gastric cancer except bypass surgery and endoscopic resection

Fair oral intake with or without bypass surgery

Sufficient organ function

WBC count  $\geq 4000/\text{mm}^3$  and  $\leq 12\,000/\text{mm}^3$

Platelet count  $\geq 100\,000/\text{mm}^3$

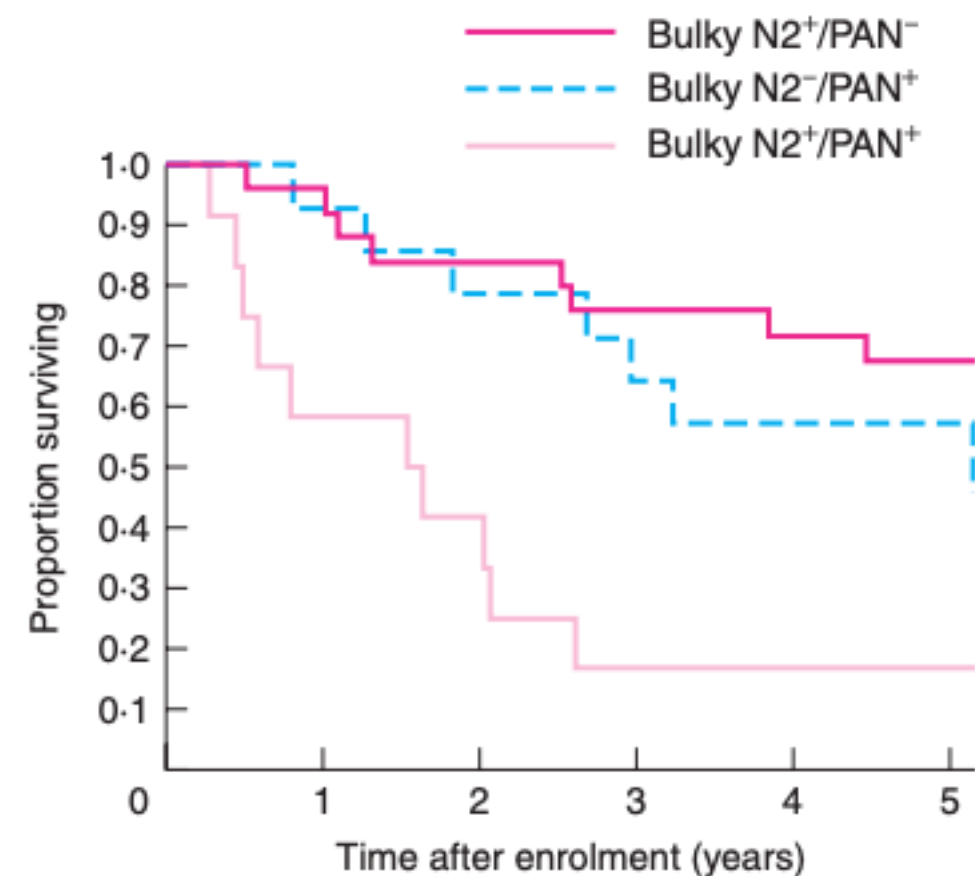
AST and ALT  $\leq 100$  units/l

Total bilirubin  $\leq 1.5$  mg/dl

Creatinine  $\leq 1.5$  mg/dl and creatinine clearance  $\geq 60$  ml/min

Haemoglobin  $\geq 8.0$  g/dl

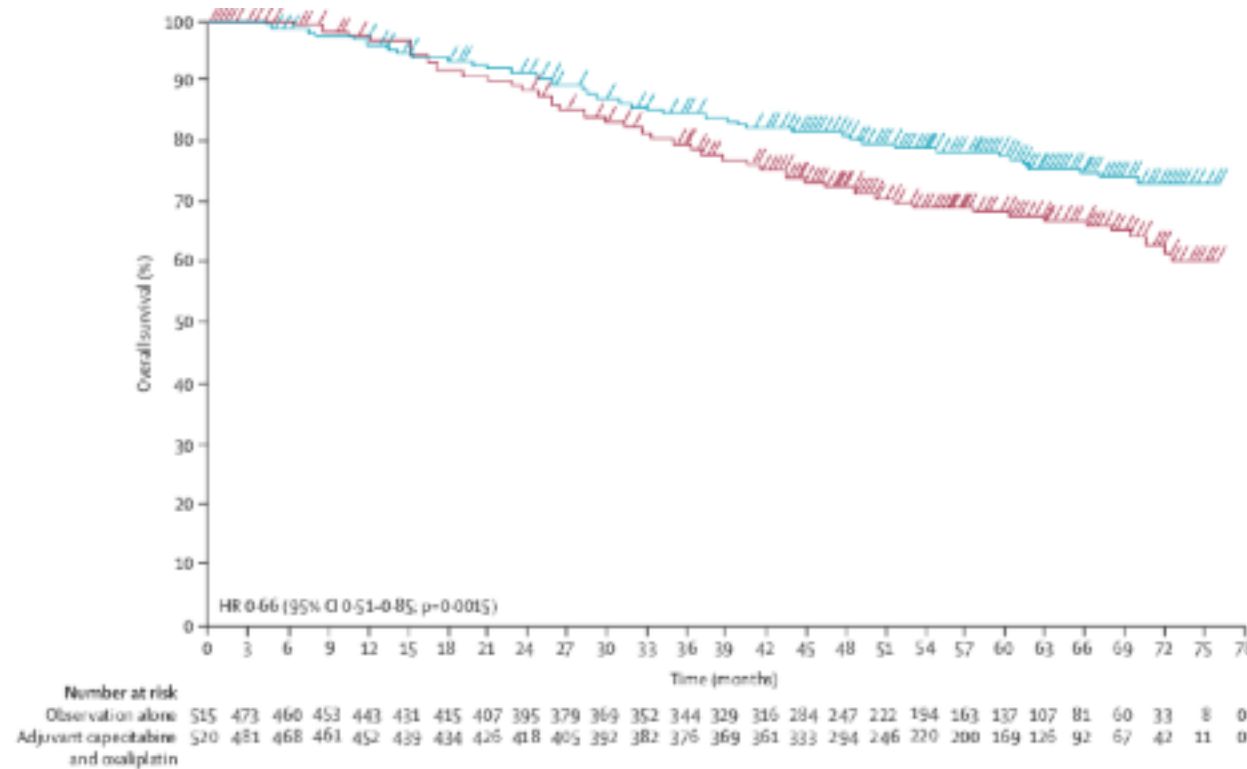
Written informed consent



# Adjuvant capecitabine plus oxaliplatin for gastric cancer after D2 gastrectomy (CLASSIC): 5-year follow-up of an open-label, randomised phase 3 trial



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The estimated 5-year overall survival 78% (95% CI 74–82) in the adjuvant CT group 69% (64–73) in the observation alone group.

|      | N   | 5-year disease-free survival          |                   |                  | 5-year overall survival               |                   |                  |
|------|-----|---------------------------------------|-------------------|------------------|---------------------------------------|-------------------|------------------|
|      |     | Adjuvant capecitabine and oxaliplatin | Observation alone | Hazard ratio     | Adjuvant capecitabine and oxaliplatin | Observation alone | Hazard ratio     |
| II   | 515 | 80% (74–85)                           | 68% (61–74)       | 0.55 (0.38–0.80) | 88% (83–92)                           | 79% (73–84)       | 0.54 (0.34–0.87) |
| IIIA | 377 | 58% (50–67)                           | 44% (35–53)       | 0.61 (0.44–0.84) | 70% (62–77)                           | 63% (55–71)       | 0.75 (0.52–1.10) |
| IIIB | 143 | 52% (40–65)                           | 21% (9–33)        | 0.52 (0.33–0.82) | 66% (54–78)                           | 45% (31–58)       | 0.67 (0.39–1.13) |

Data are % (95% CI) or hazard ratio (95% CI).

**Table 3: Disease-free survival and overall survival by disease stage in the intention-to-treat population**