Adjuvant capecitabine for biliary tract cancer: The BILCAP randomized study

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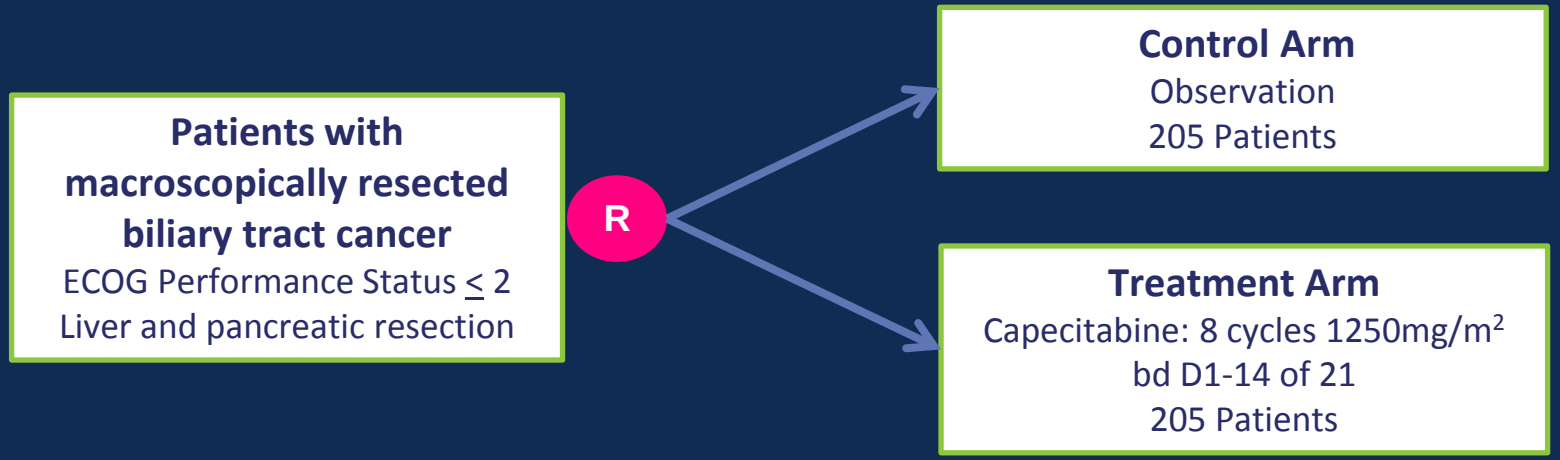
PRESENTED AT: ASCO ANNUAL MEETING '17 | #ASCO17

Trial Design



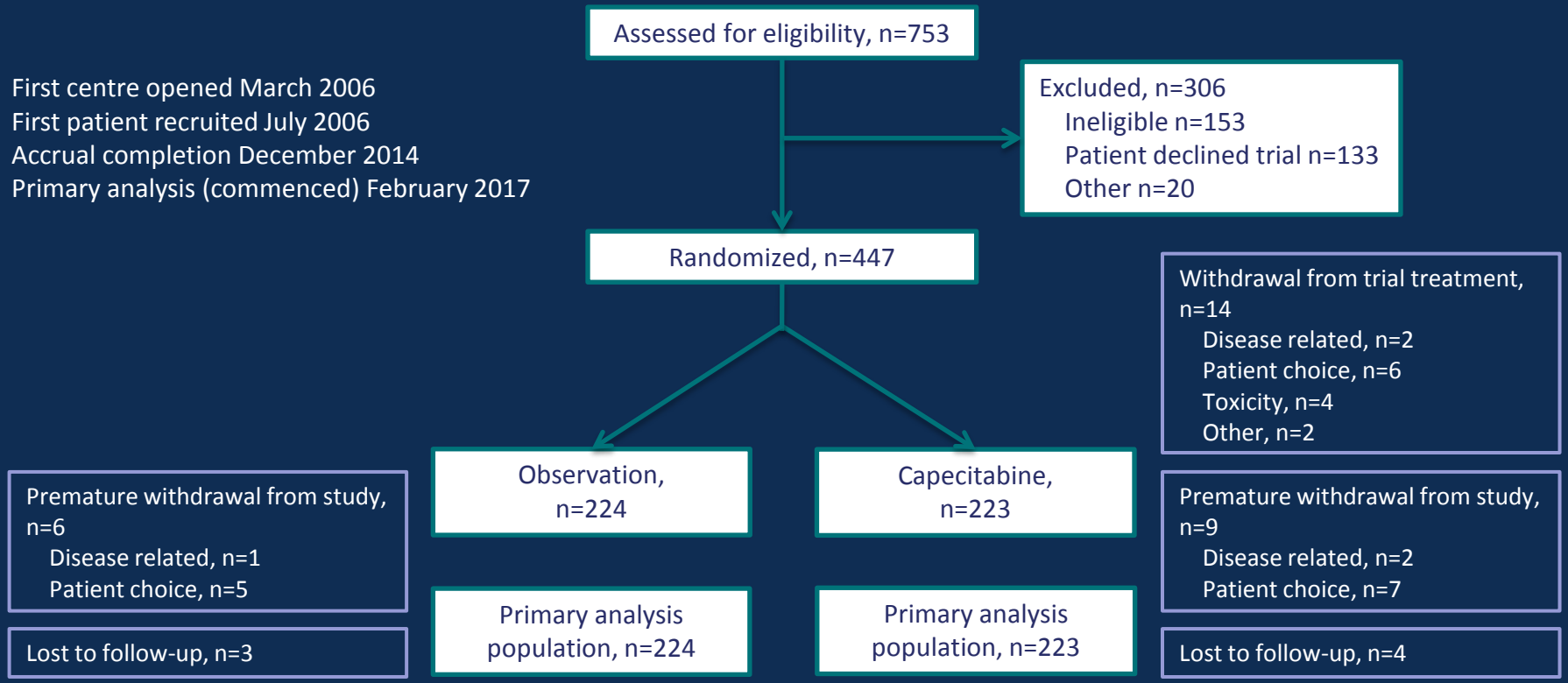
Primary endpoint: **Overall Survival**

Secondary endpoints: Relapse free survival, toxicity, QoL and health economics

Statistics: To detect a 31% reduction in risk (HR 0.69) with 2-sided significance level of 5% and 80% power, required 410 patients (234 events)

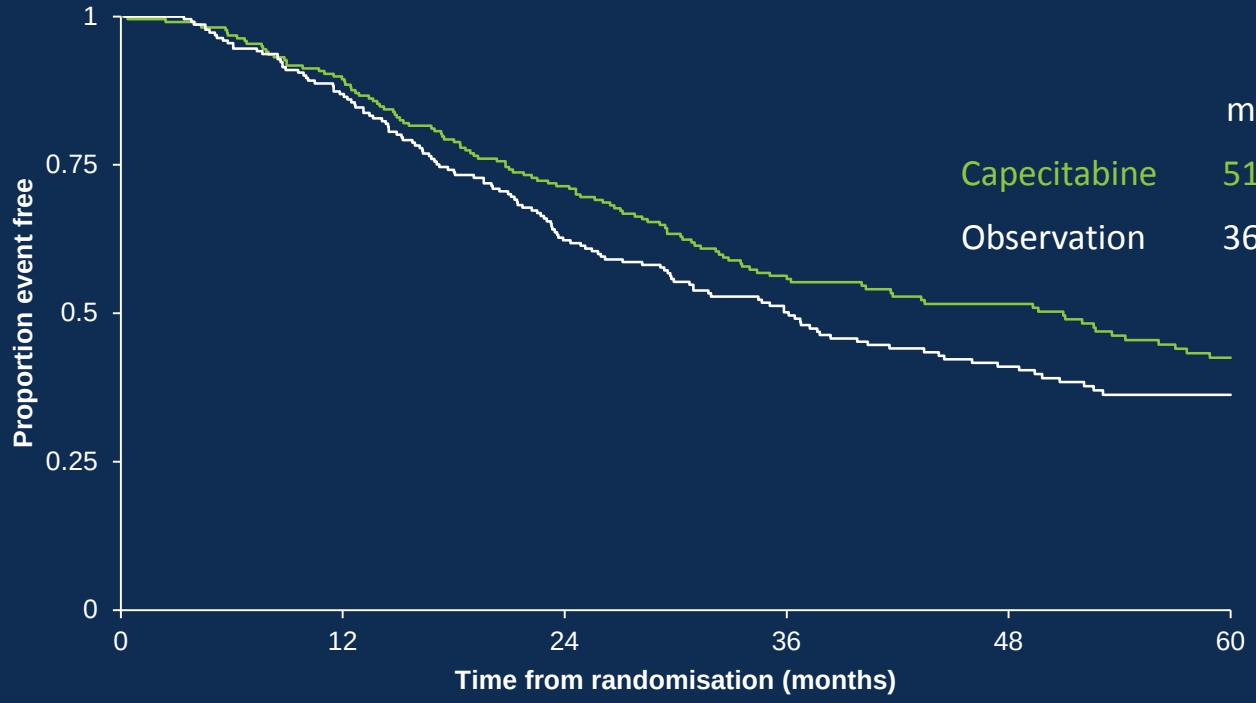
Participant flow

First centre opened March 2006
First patient recruited July 2006
Accrual completion December 2014
Primary analysis (commenced) February 2017



Overall Survival (ITT)

>80% of patients followed up for 36 months



	Median OS months (95%CI)	HR (95%CI)
Capecitabine	51.1 (34.6, 59.1)	HR 0.81 (0.63, 1.04) p=0.097
Observation	36.4 (29.7, 44.5)	

Sensitivity analyses adjusting prognosticators [$]

HR 0.70 95%CI (0.55, 0.91) p=0.007

[$]Nodal status, Disease Grade, Gender

Toxicity

The safety population was conditional on receiving capecitabine (n=213)

There were no deaths related to chemotherapy

Toxicity type	Grade 3/4
Fatigue	16 (7.5 %)
Plantar palmar erythrema	44 (20.7 %)
Diarrhea	16 (7.5 %)
Nausea	2 (0.9 %)
Mucositis/stomatitis	2 (0.9 %)
Vomiting	1 (0.5 %)
Neutropenia	4 (1.9 %)
Bilirubin	3 (1.4 %)
Thrombocytopenia	1 (0.5 %)
Alopecia	0

Conclusions

- Capecitabine compared to surveillance improves median overall survival in resected biliary tract cancer from 36 to 53 months
- The toxicities were modest
- Capecitabine should become the standard of care for patients following curative resection of biliary tract cancer