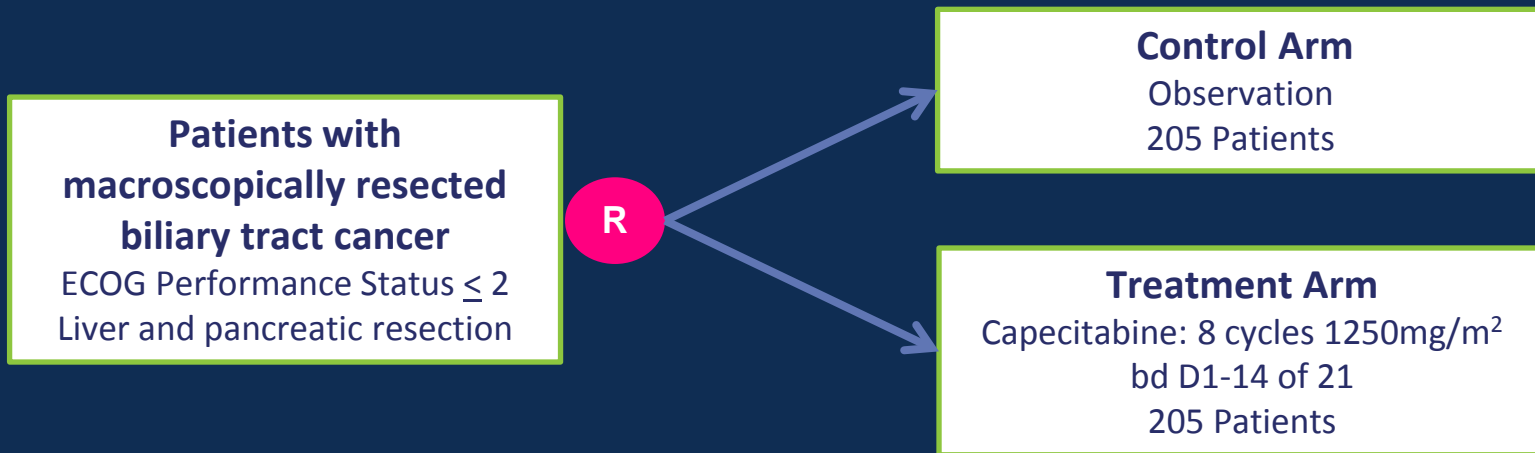


Adjuvant capecitabine for biliary tract cancer: The BILCAP randomized study

John Primrose, Richard Fox, Juan Valle, Daniel Palmer, Raj Prasad, Darius Mirza, Alan Anthony, Philippa Corrie, Stephen Falk, Harpreet Wasan, Paul Ross, Lucy Wall, Jonathan Wadsley, Jeffrey Evans, Deborah Stocken, Raaj Praseedom, David Cunningham, James Garden, Clive Stubbs and John Bridgewater on behalf of the BILCAP investigators



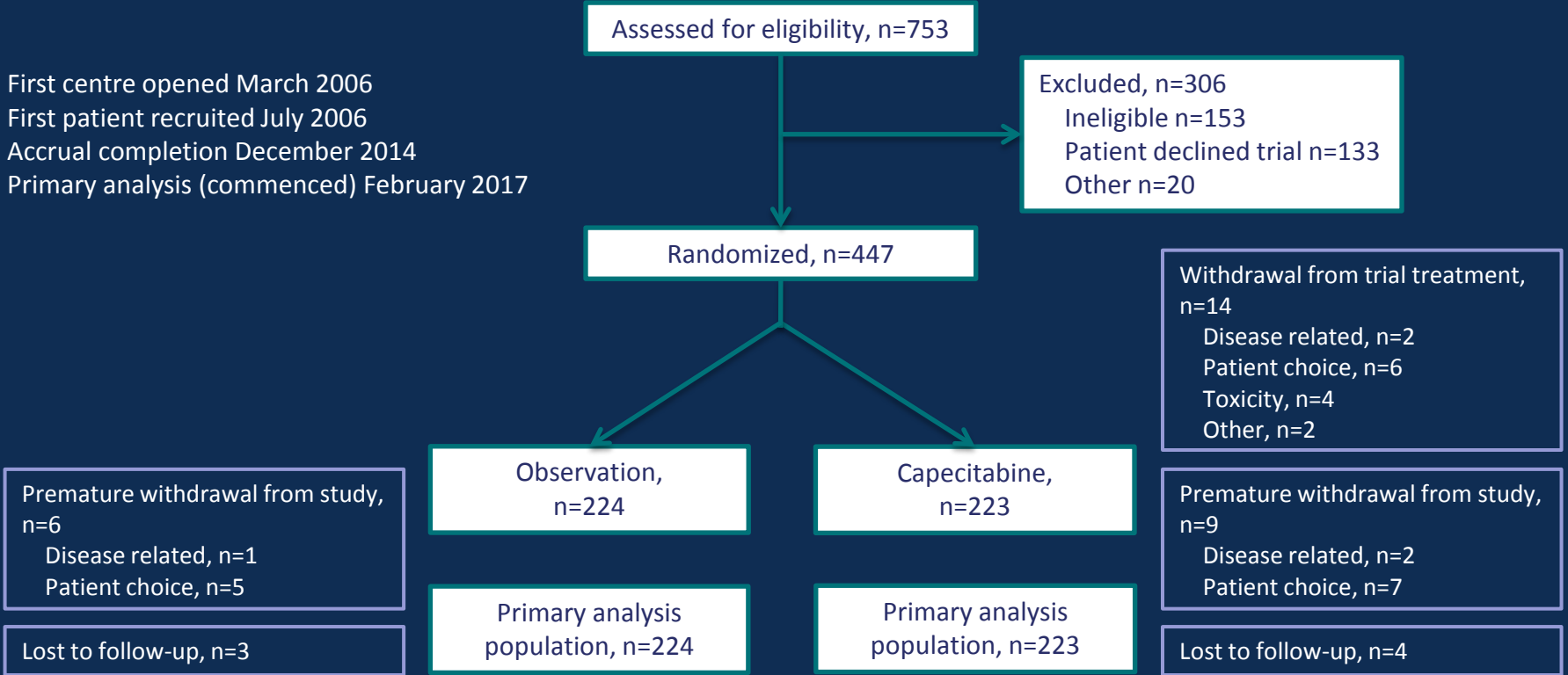
Primary endpoint: Overall Survival

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)

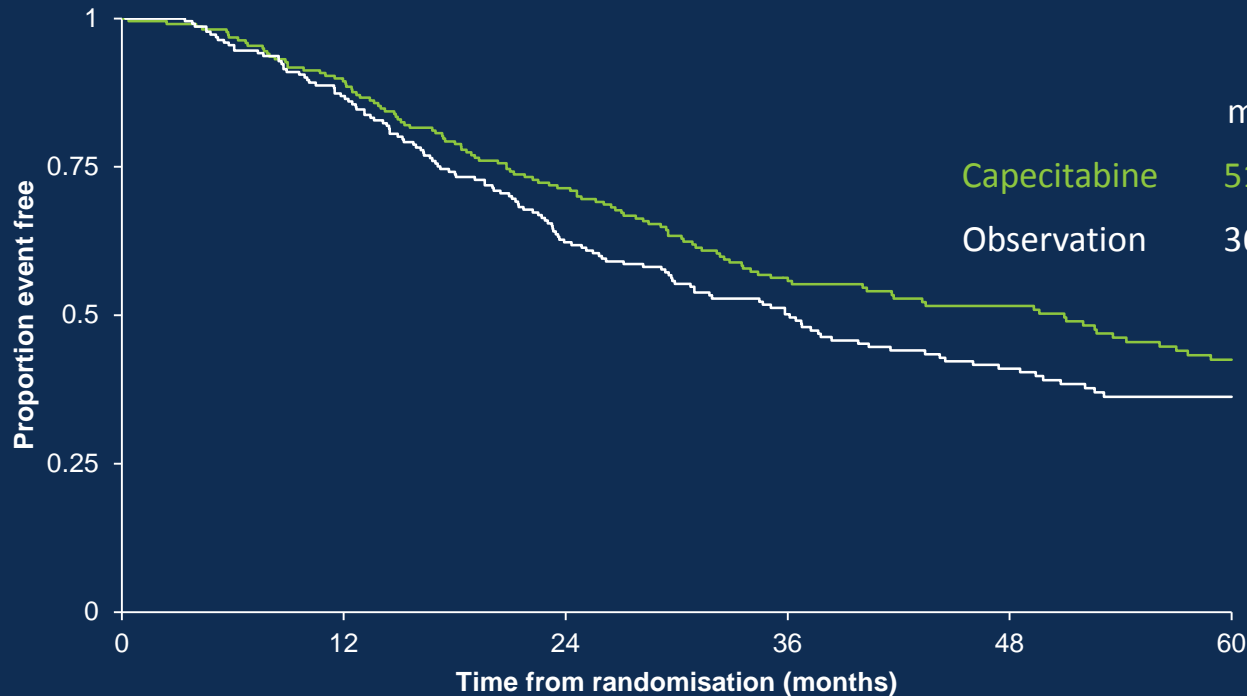
Participant flow

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)

Observation

36.4 (29.7, 44.5)

p=0.097

Sensitivity analyses adjusting
prognosticators[§]

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

[§]Nodal status, Disease Grade, Gender

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

- 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