RANDOMIZATION
Randomized n=909
Eligible n=873

Arm A: LV + 5FU + irinotecan
Allocated to intervention (n=441)
Received allocated intervention (n=423)
Did not receive allocated intervention (n=18)
Reasons: Lost files (n=8)
Never starters (n=6)
Received intervention of Group B (n=4)

Completion (n=350)
Discontinued intervention (n=77)
Reasons: Death (n=3)
Non-fatal toxicity (n=14)
Doctor’s decision (n=4)
Progression (n=5)
Voluntary withdrawal (n=30)
Other (n=16)
Unknown (n=5)

Dead (n=118)
Still on follow-up (n=311)
Lost to follow-up* (n=12)

Arm B: LV + 5FU
Allocated to intervention (n=432)
Received allocated intervention (n=414)
Did not receive allocated intervention (n=18)
Reasons: Lost files (n=6)
Never starters (n=8)
Received intervention of Group A (n=4)

Completion (n=347)
Discontinued intervention (n=71)
Reasons: Death (n=3)
Non-fatal toxicity (n=10)
Doctor’s decision (n=2)
Progression (n=10)
Voluntary withdrawal (n=31)
Other (n=9)
Unknown (n=6)

Dead (n=128)
Still on follow-up (n=297)
Lost to follow-up* (n=7)

*When followed-up for less than 4 years