

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)

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=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)

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=118)

Still on follow-up (n=311)

Lost to follow-up* (n=12)

Dead (n=128)

Still on follow-up (n=297)

Lost to follow-up* (n=7)