

BACKGROUND

- ## METHODS

The flowchart illustrates the clinical trial design, starting with a randomization of 356 patients (R 1:4) into Group A (N=71) and Group B (N=285). Group A receives two cycles of TCHP (TCHP x2, TCHP x4) followed by 12 cycles of PH (ETx) (PH (ETx) x12). Group B receives two cycles of PH (ETx) (PH (ETx)* x2) followed by a PET (Total Body) Scan. Based on the PET scan results, Group B is stratified into 'Response' and 'No Response' groups. The 'Response' group receives 6 cycles of PH (ETx) (PH (ETx) x6), while the 'No Response' group receives 6 cycles of TCHP (TCHP x6). Both groups then undergo surgery. Post-surgery, the 'Response' group is further stratified into 'pCR' and 'Non-pCR' groups. The 'pCR' group receives 10 cycles of PH (ETx) (PH (ETx) x10), while the 'Non-pCR' group receives 4 cycles of TCHP (ETx) (TCHP x6 - PH (ETx) x4) followed by 10 cycles of PH (ETx) (PH (ETx) x10). The trial includes two primary endpoints: the First Primary Endpoint (pCR in PET Responders (Group B)) and the Second Primary Endpoint (3-year iDFS rate in Group B).

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graph LR
    R((R 1:4  
N=356)) -->|Group A| A[TCHP x2  
N=71]
    R -->|Group B| B[PH (ETx)* x2  
N=285]
    A --> C[TCHP x4]
    C --> D[PH (ETx) x12]
    D --> E[First Primary Endpoint]
    B --> F[PET Total Body Scan]
    F -->|Response| G[PH (ETx) x6]
    F -->|No Response| H[TCHP x6]
    G --> I[SURGERY]
    H --> I
    I -->|pCR| J[PH (ETx) x10]
    I -->|Non-pCR| K[TCHP x6 - PH (ETx) x4]
    K --> L[PH (ETx) x10]
    J --> M[Second Primary Endpoint]
    L --> M
    
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RESULTS

- | ns | Group B (N=285) | | | |
|----------|---------------------------------------|-------------------------|---|-------------------------|
| | PET response after 2 cycles (227/285) | | No PET response after 2 cycles (58/285) | |
| | No neoadjuvant CT | | Neoadjuvant CT | |
| | MRI reduction (N=200) | No MRI reduction (N=27) | MRI reduction (N=35) | No MRI reduction (N=23) |
| pCR | 39.0%
(78/200) | 29.6%
(8/27) | 28.0%
(10/35) | 21.7%
(5/23) |
| 3-y iDFS | 95.1% | 96.3% | 100% | 75.3% |

CONCLUSIONS

- ## ACKNOWLEDGEMENTS AND AUTHOR INFORMATION

BIBLIOGRAPHY

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