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Pharmacokinetic Modulation of Osimertinib Using Itraconazole to Enable Reduced Dosing Frequency- 'Rohtak Regimen'/CAROL Trial (CTRI/2025/07/090989)

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Science Without Boundaries: **Uniting the World Against Thoracic Cancer**

Disclosure

Mandatory for Oral/Mini-Oral Presentation

- No Disclosures to be made
- No Conflict of Interest

Artificial Intelligence (AI) Use Disclaimer

No Artificial Intelligence tool has been used in the conduct of this research or for making of the presentation.

Background

- Osimertinib is standard therapy for EGFR-mutant NSCLC
- Daily 80-mg dosing provides sustained therapeutic exposure
- High treatment cost remains a major barrier to access
- Osimertinib is substantially metabolized through CYP3A4
- CYP3A4 inhibition with itraconazole may increase systemic exposure
- ***Hypothesis: Pharmacokinetic boosting may permit less frequent osimertinib dosing while maintaining exposure***

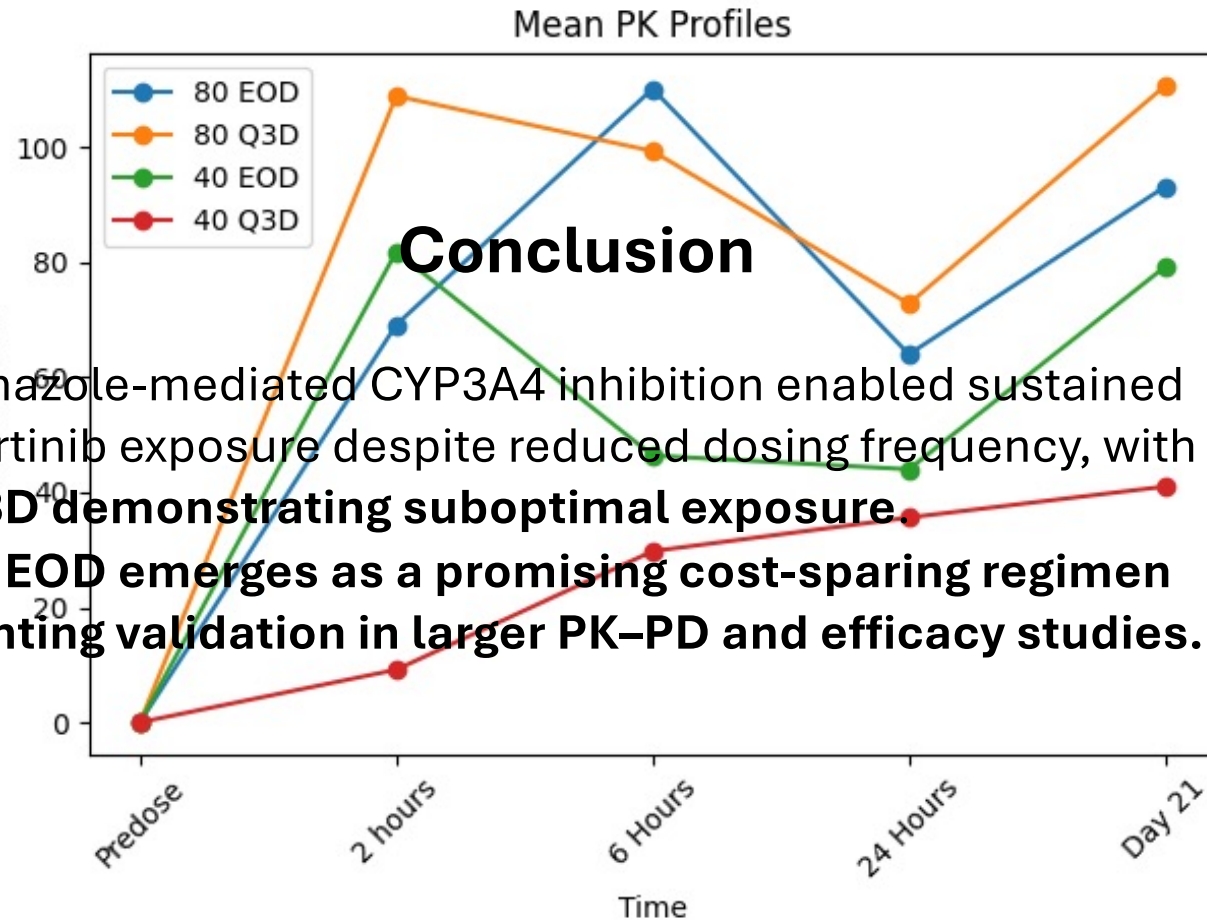
Study Design

- Open Label, randomized pharmacokinetic study
- Phase I- 3+3 dose-escalation framework
- 14 patients screened → 12 randomized
- 4 groups- 3 patients/group
- Itraconazole Supra-bioavailable 130mg BD BID × 7 days → CYP3A4 inhibition
- Maintenance OD dose thereafter
- Osimertinib initiated on Day 8
- PK assessment after 7 days of osimertinib therapy
- PK Time Endpoints-
 1. AUC₀₋₂₄
 2. C-trough
 3. Plasma Conc. Derived using LC-MS

Study Participants

Characteristic	80 mg EOD (n=3)	80 mg Q3D (n=3)	40 mg EOD (n=3)	40 mg Q3D (n=3)
Mean age, years	47.7	55.7	62.0	61.0
Female, %	33	100	100	100
Stage IV, %	66.7	100	100	33
Osimertinib as 2nd line, %	66.6	66.6	33	66.6
Brain metastasis, %	33	33	33	0
ORR, %	66.7	100	66.7	100

Results

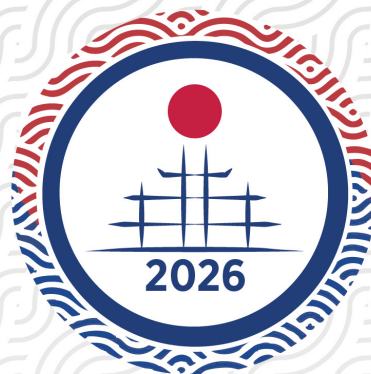


Paramete
AUC₀₋₂₄
C_{trough}

ng Q3D
675.6
41.0

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Thank You.

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