Poster No.: 2928

Three-day doxycycline for uncomplicated *Chlamydia trachomatis* in men who have sex with men: a single-arm, open-label interventional study

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1. INTRODUCTION

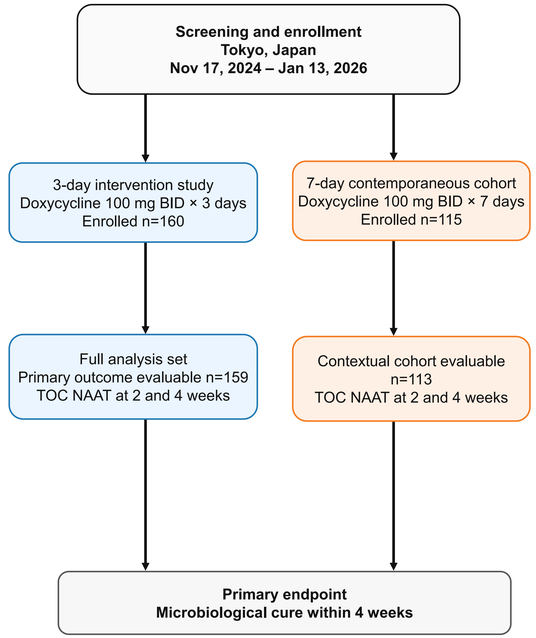
- *Chlamydia trachomatis* remains a common bacterial STI worldwide and is highly prevalent among MSM.
- Extragenital infection, especially rectal infection, is common in MSM.
- International guidelines recommend doxycycline 100 mg twice daily for 7 days as first-line therapy for uncomplicated infection.
- Adherence to multi-day doxycycline regimens may be suboptimal in real-world settings.
- A 3-day doxycycline regimen has pharmacologic plausibility, but prospective evidence in MSM has been lacking.

2. METHODS

- Open-label single-arm interventional study in Tokyo, Japan.
- Adults aged ≥18 years with urogenital and/or extragenital *C. trachomatis* detected by NAAT.
- Doxycycline 100 mg twice daily for 3 days.
- Test-of-cure NAAT scheduled at 2 and 4 weeks after treatment completion.
- Prespecified primary endpoint: microbiological cure within 4 weeks.
- Non-randomized contemporaneous 7-day doxycycline cohort included for descriptive contextual comparison only.

Trial registration: jRCTs031240353.
Ethics approval: NCGM-C-004884-01.

Study Design and Cohort Flow



BID = twice daily; TOC = test-of-cure; NAAT = nucleic acid amplification test

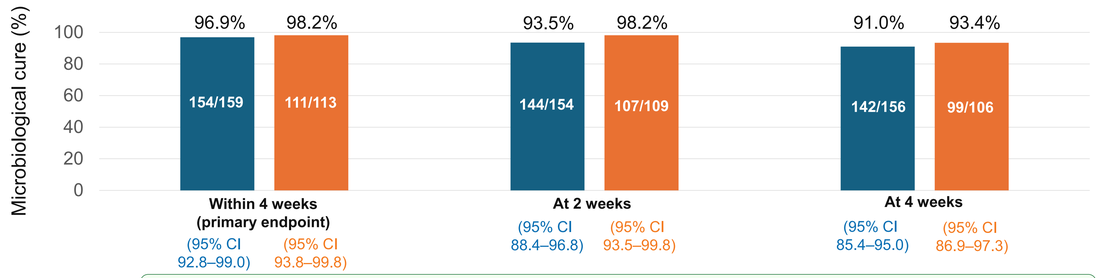
3. RESULTS

A. Baseline snapshot

	3-day study (n=160)	7-day cohort (descriptive) (n=115)
Primary analysis set	**159**	**113**
Median age, years (IQR)	36 (32–45)	39 (33–49)
HIV infection, n (%)	71 (44.4)	54 (47.0)
Rectal chlamydia, n (%)	134 (83.8)	96 (83.5)
Pharyngeal chlamydia, n (%)	20 (12.5)	10 (8.7)
Urogenital chlamydia, n (%)	21 (13.1)	18 (15.7)
Multisite infection, n (%)	17 (10.6)	11 (9.6)

B. Overall microbiological cure outcomes

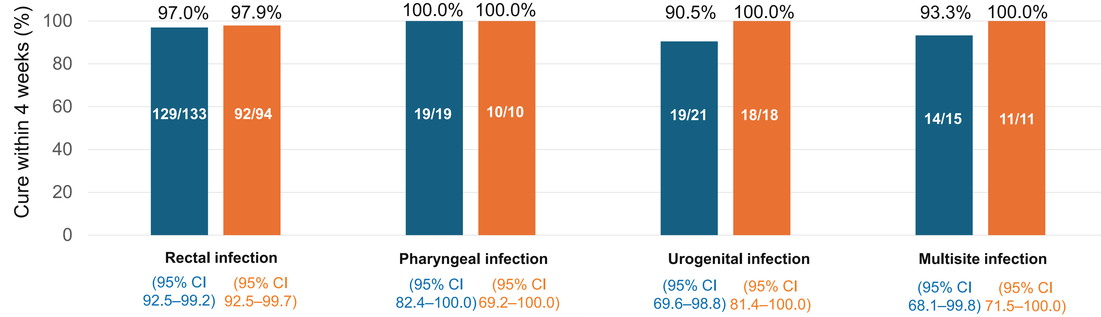
7-day cohort is a descriptive contextual cohort.



✓ Primary endpoint (within 4 weeks): 96.9% cure in the 3-day study exceeds the prespecified 90% success threshold.

C. Site-specific microbiological cure within 4 weeks

7-day cohort is a descriptive contextual cohort.

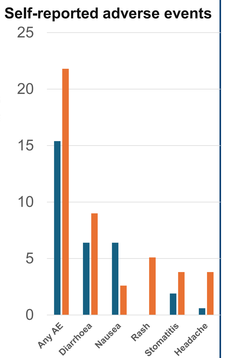


D. Adherence and safety (3-day study)

Adherence (3-day study)
- Completed all doses 141/154 (91.6%)
- Non-adherence:
  1 missed dose in 11 participants
  2 missed doses in 2 participants

Self-reported adverse events (3-day study)
- Any AE: 24/156 (15.4%)
- All AEs were mild and self-limiting

7-day cohort (descriptive context)
- Any AE: 17/78 (21.8%)



Percentages based on participants with available safety data.

Key message: The 3-day regimen achieved high microbiological cure and was generally well tolerated.

4. DISCUSSION / INTERPRETATION

- This study provides prospective evidence for a 3-day doxycycline regimen in MSM, a population with predominantly rectal infection.
- Pharmacokinetic plausibility and sustained mucosal exposure support the biological rationale for shortened therapy.
- The contextual 7-day cohort was not randomized and should be interpreted only as descriptive evidence, not a formal comparator.
- Later positive conversion after earlier clearance should be interpreted cautiously in a population at ongoing risk of reinfection.

5. CONCLUSIONS

✓ **A 3-day doxycycline regimen achieved high microbiological cure in MSM with uncomplicated C. trachomatis infection.**

Tolerability was good and adverse events were mild and self-limiting.

Randomized non-inferiority trials are needed before shortened therapy can be considered an alternative to the standard 7-day regimen.

6. REFERENCES

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Funding: National Center for Global Health and Medicine (23A2004).

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