**Results.** A total of 134 participants were randomized to each treatment group. Demographics and baseline characteristics were generally well balanced between treatment groups (Table 1). The median (range) age in the ITT population was 50 (18-75) years and 61% were men. The overall frequency of infection was the appendix (C/T + MTZ, 27.6%; MEM + pbo, 28.1%); overall, the most frequently isolated pathogens were Escherichia coli (61.4%) and Klebsiella pneumoniae (17.3%); few anaerobes were isolated (Table 1). C/T + MTZ was non-inferior to MEM + pbo for clinical cure in the CE population (C/T + MTZ, 95.2%; MEM + pbo, 93.1%; difference, 2.1% [95% CI, −4.7% to 8.8%]). Results for key secondary endpoints were comparable between treatment groups (Table 2). Rates of AEs were generally similar between treatment groups (Table 3).

**Conclusion.** C/T + MTZ was non-inferior to MEM + pbo in the treatment of adult Chinese participants with cIAI and demonstrated a favorable safety profile.

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### Table 1. Participant Demographics and Baseline Characteristics (ITT and EEM Populations)

| Characteristic                          | C/T + MTZ (n=134) | MEM + pbo (n=134) | p-value |
|----------------------------------------|-------------------|-------------------|---------|
| Age, median (range)                    | 50 (18-75)        | 50 (18-75)        | 0.951   |
| Sex, female (%)                        | 35 (26.0%)        | 37 (27.6%)        | 0.634   |
| Median (range)                         | 61 (18-75)        | 61 (18-75)        | 0.545   |
| APACHE II, median (range)              | 5.0 (4.0-6.0)     | 5.0 (4.0-6.0)     | 0.695   |
| C/T + MTZ vs MEM + pbo                 |                   |                   |         |
| Difference (95% CI)                    | 0.10 (-0.23 to 0.43) | 0.09 (-0.24 to 0.33) | 0.560   |

### Table 2. Efficacy Outcomes

| Efficacy endpoint, n (%)                | C/T + MTZ (n=134) | MEM + pbo (n=134) | % Difference C/T + MTZ vs MEM + pbo (95% CI) |
|----------------------------------------|-------------------|-------------------|--------------------------------------------|
| Clinical recurrence at TOC (ITT population)* | 10 (7.5%)         | 10 (7.5%)         | 0.00 (95% CI 0.00-0.01)                     |
| Clinical cure                          | 109 (82.3%)       | 109 (82.3%)       | 0.00 (95% CI 0.00-0.01)                     |
| Clinical failure                        | 5 (3.7%)          | 6 (4.5%)          | 0.00 (95% CI 0.00-0.05)                     |
| Clinical recurrence at TOC (ITT population)* | 124 (92.5%)       | 124 (92.5%)       | 0.00 (95% CI 0.00-0.01)                     |
| Clinical cure                          | 124 (92.5%)       | 124 (92.5%)       | 0.00 (95% CI 0.00-0.01)                     |
| Clinical failure                        | 5 (3.7%)          | 6 (4.5%)          | 0.00 (95% CI 0.00-0.05)                     |
| Clinical recurrence at TOC (ITT population)* | 131 (97.7%)       | 131 (97.7%)       | 0.00 (95% CI 0.00-0.01)                     |
| Clinical cure                          | 131 (97.7%)       | 131 (97.7%)       | 0.00 (95% CI 0.00-0.01)                     |
| Clinical failure                        | 5 (3.7%)          | 6 (4.5%)          | 0.00 (95% CI 0.00-0.05)                     |

### Table 3. Summary of Adverse Events (All Participants as Treated Population)

| ATE category | C/T + MTZ (n=134) | MEM + pbo (n=134) | % Difference C/T + MTZ vs MEM + pbo (95% CI) |
|--------------|-------------------|-------------------|--------------------------------------------|
| Total AEs    |                   |                   |                                            |
| Serious AEs  |                   |                   |                                            |
| AEs leading to death |                   |                   |                                            |

**Results.** There were 247 unique episodes of PJI in 237 patients during the study period. Parenteral antibiotics were given in 99.2% of cases (n=245). This was followed by chronic oral antibiotic suppression in 92.2% (n=226) with a median duration of 2.2 years (1.0-4.1).

**Conclusion.** Debridement, antibiotics, and implant retention (DAIR) is appropriate for select acute postoperative and hematogenous periprosthetic joint infections (PJIs). However, the optimal duration of antimicrobial therapy in patients treated with DAIR has not been defined. Therefore, we aimed to identify the ideal duration of parenteral and oral antibiotics after DAIR.

**Methods.** We performed a retrospective study of patients >18 years of age with hip or knee PJI managed with DAIR between January 1, 2008, and December 31, 2018, at Mayo Clinic. PJI was defined using criteria adapted from the International Consensus Meeting on PJI. The outcome was defined as either PJI recurrence or unplanned reoperation due to infection. Joint-stratified Cox proportional hazards regression models with time-dependent covariates were used to assess nonlinear effects of antibiotic duration. Hazard ratios were computed based on prespecified time points for comparison, whereas p-values represented the overall effect across the entire range of durations.

**Results.** The duration of antibiotic therapy after debridement and implant retention in patients with Periprosthetic Joint Infections

**Background.** Debridement, antibiotics, and implant retention (DAIR) is appropriate for select acute postoperative and hematogenous periprosthetic joint infections (PJIs). However, the optimal duration of antimicrobial therapy in patients treated with DAIR has not been defined. Therefore, we aimed to identify the ideal duration of parenteral and oral antibiotics after DAIR.
Conclusion. After DAIR, efficacy from four weeks of parenteral antibiotics was no different from six weeks when followed by chronic oral antibiotic suppression. Our results could not establish an optimal duration but suggested that continuing suppressions portends a lower risk of failure of DAIR.

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112. A Rapid Host-Protein Signature Based on TNF-related Apoptosis-Induced Ligand (TRAIL), Interferon Gamma Induced Protein-10 (IP-10) and C-Reactive Protein (CRP) Accurately Differentiates Between Bacterial and Viral Infection in Febrile Children: Apollo Sub-Study

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Background. Identifying infectious etiology is essential for appropriate patient management, including antibiotic use. A host-protein signature for differentiating bacterial from viral infection has exhibited robust performance (AUC of 0.9, 95% CI 0.86-0.95) in prior studies. Performance data was lacking for a broad pediatric population recruited in emergency departments (EDs) and urgent care centers (UCCs).

Methods. Non-immunocompromised children were recruited prospectively from 5 EDs and 3 UCCs in the U.S. and 1 ED in Israel between May 2019 and August 2020. Eligibility required physician’s clinical suspicion of acute infection and reported fever. Reference standard etiology was adjudicated by experts based on clinical, laboratory, radiological, microbiological and follow-up data. For the primary analysis, experts blinded to one another, to the host-sigature results and also to procacinol and CRP, classified cases as bacterial or viral. For the secondary analysis, experts blinded to one another and the host signature results, were permitted to classify cases as bacterial, viral or indeterminate; indeterminates were removed from the secondary analysis. Host signature (comprising TRAIL, IP-10 and CRP; MeMed BV®) was measured using a rapid platform (MeMed Key®) generating a bacterial likelihood score (0-100) in 15 minutes.

Results. The study cohort comprised 162 children (median age, 5.5 yrs; interquartile range, 8.5), of whom 69 (43%) presented within 2 days of symptom onset and 37 (23%) were hospitalized for a median of 3 days. Respiratory tract infection was the predominant syndrome (11% lower and 44% upper). Host signature attained AUC 0.87 (0.74-1) and 0.92 (0.79-1) in the primary and secondary analysis, respectively. With higher the signature score, there was a significantly higher likelihood of bacterial infection (p< 0.001; Table 1). The 3 bacterial infections assigned score < 35 (false negative) would have been identifiable by physical examination (Table 2).

Increasing host signature score is associated with increasing likelihood of bacterial infection across both the primary and secondary cohort.

| Host signature score bins | % patients | % patients | % Bacterial infection in all patients | % Bacterial infection in bacterial patients | % Viral infection in viral patients | % Viral infection in all patients | % Bacterial reference standard patients | % Viral reference standard patients |
|--------------------------|-----------|-----------|-------------------------------------|-------------------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|-----------------------------------|
| 0 ≤ score ≤ 35 | 7 | 6.5% | 1 | 1 | 42% | 58% | 0.87 (0.83-0.90) |
| 36 ≤ score ≤ 80 | 12 | 7.4% | 2 | 16.7% | 10 | 85.3% | 2.50 (2.0-3.1) |
| 81 ≤ score ≤ 125 | 12 | 10.3% | 1 | 10.3% | 1 | 90.3% | 6.00 (5.2-6.7) |
| 126 ≤ score ≤ 175 | 19 | 11.7% | 0 | 0% | 0 | 100% | 0.00 |
| > 175 | 111 | 68.3% | 3 | 2.7% | 109 | 97.3% | 0.04 (0.03-0.05) |

Primary cohort

Secondary cohort

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Conclusion. The host-protein signature measured using a rapid platform attained robust performance in differentiating bacterial vs viral infection in children with acute febrile illness, supporting its potential to enhance rational use of antibiotics in the ED and UCC.

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113. Reliability of Nasopharyngeal PCR for the Detection of Otopathogens in Children with Uncomplicated Acute Otitis Media

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