Supplementary Online Content

Moran GJ, Krishnadasan A, Mower WR, et al. Effect of cephalexin plus trimethoprim-sulfamethoxazole vs. cephalexin alone on clinical cure of uncomplicated cellulitis: a randomized clinical trial. *JAMA*. doi:10.1001/jama.2017.5653

This supplementary material has been provided by the authors to give readers additional information about their work.

eAppendix. Supplemental Methods

Study Sites

Study sites were emergency departments at Olive View-UCLA [Sylmar, CA], Maricopa [Phoenix, AZ], Temple University [Philadelphia, PA], Johns Hopkins University [Baltimore, MD], and Truman [Kansas City, MO] Medical Centers.

Study Conduct

An independent data and safety monitoring board (DSMB) provided oversight. Interim analyses occurred at 50% and 75% of anticipated enrollment. These interim analyses were designed to assess efficacy and futility, and evaluated all other endpoints, including safety data, and provided guidance in determining whether there was overwhelming evidence that would justify early termination. In addition, the interim analyses provided the investigators with information to enhance sample size estimation and ensured that the trial would attain sufficient power to produce meaningful results. All interim efficacy analyses were based on the Per Protocol outcomes and participants were classified based on assessments at the TOC. There were no safety concerns or indications for early termination at the interim analyses, and no revision of sample size. The principal investigative site (Olive View-UCLA) conducted periodic quality assurance audits at all sites. The National Institutes of Health contracted organizations to prepare and distribute study drugs (Fisher Clinical Services, Allentown, PA), manage randomization, blinding, specimen shipments, study data, and materials (The Emmes Corporation, Rockville, MD), and provide regulatory oversight (ICON, Chicago, IL, and PPD, Wilmington, NC). All authors assume

responsibility for the manuscript's accuracy and vouch for its completeness and fidelity to the study protocol.

Exclusion Criteria

We excluded patients with the following conditions: indwelling device; suspected osteomyelitis or septic arthritis; diabetic foot, decubitus, or ischemic ulcer; mammalian bite; wound with organic foreign body; infection of another organ system/site; perirectal, perineal or paronychial location; intravenous drug use within previous month and fever; underlying skin condition in the area of infection (e.g., active eczema, psoriasis, venous stasis dermatitis); long-term care residence; incarceration; immunodeficiency (e.g., absolute neutrophil count <500/mm^3, immunosuppressive drugs, active chemotherapy, or known AIDS assessed by participant history); creatinine clearance <50 mL/min; surgical exploration to rule out abscess, even if negative (negative needle aspiration was acceptable); allergy or intolerance to cephalosporins or trimethoprim-sulfamethoxazole; taking warfarin, phenytoin, or methotrexate; known G-6-PD or folic acid deficiency; pregnant or lactating; treatment with cephalexin or trimethoprim-sulfamethoxazole within 48 hours; concurrent treatment with topical or systemic antibiotic; or enrolled in the study within 12 weeks. Laboratory testing was done at the discretion of the treating clinician.

Study Medication

The placebo was Avicel PH-102 white microcrystalline cellulose encapsulated in Capusugel DBcaps size AAel gray color 2945 opaque. Both the active drugs and placebo were encapsulated using the same capsule. Trimethoprim-sulfamethoxazole 80 mg/400 mg used the Avicel as a filler agent. Cephalexin 500 mg did not require any filler due to its

large size. After manufacture using the gray DBcaps, all clinical material looked the same and felt the same while being held in the hand. If you weighed the capsules on a precision scale there were minor differences in weight, essentially undetectable without a scale. All medications and placebo were purchased. That activity had no impact on protocol design or any other aspect of the study besides, other than cost.

Measurement of Lesion Characteristics

Measurement of Erythema, Induration, Swelling, and Tenderness

All measurements were taken while the infected area was in a nondependent position, e.g., if infection was on the leg, the participant was lying down, not sitting or standing. It was required that all infections have measurement of erythema upon enrollment and subsequent follow-up visits. The border of erythema was marked with a pen at the initial visit and used for comparison at subsequent assessments. Maximal dimensions of erythema, both width and length, were recorded in centimeters. Investigators attempted to find the infection edge that best distinguished erythema from non-erythematous skin. Erythema was measured in the dimension of maximal length. The maximal width was measured perpendicular to the axis of the maximal length. The maximal width measurement did not have to be in the center if the area of erythema was irregular.

The induration measurement recorded on the source documents was the outer margins of induration. Investigators attempted to find the edge that best distinguished indurated from non-indurated skin. Tenderness was assessed by patient report and clinician assessment. At all follow-up visits, presence of tenderness to palpation was recorded as “Yes” or

"Minimal/None." In addition, at the on-therapy visit, participants were asked if their tenderness was worse from baseline ("Yes" or "No"). At the end-of-therapy visit, participants were asked if there was improvement in their tenderness from baseline ("Yes" or "No").

Inter-observer Agreement Methods

The trial employed the difference in clinical cure rates as the primary outcome. To determine the reliability and reproducibility of our clinical cure assessments, we had two separate clinicians perform independent evaluations of each participant for failure (see definitions for failure Table 1 of original article) at the follow-up visits, Days 2-3 (on-therapy [OTV]), Days 7-10 (end-of-therapy [EOT]), and Days 14-21 (test-of-cure [TOC]). We used a convenience sample based on availability of two clinicians to do these assessments.

For the OTV evaluations we had separate clinicians record whether there was an increase in either the length or width of erythema greater than 25%, and whether there was worsening in both swelling and tenderness. At the EOT visit, separate clinicians independently recorded whether there was any improvement in erythema since baseline at enrollment, and whether there was any improvement in both swelling and tenderness. At the TOC visit, we had separate clinicians record the presence or absence of erythema, swelling, and tenderness (see definitions for failure Table 1 of original article). Dichotomous responses were recorded as "Yes" or "No" and "Present" or "Absent." We assessed agreement using Cohen's Kappa. The first clinician's assessment was determinative for the purposes of study data and participant outcome.

eTable 1. Inter-observer Agreement on Characteristics Defining Clinical Failure at Follow-up Visits

Visit	Clinical Failure Characteristic	Number of participants by observer response*				Raw Agreement	Cohen's Kappa
		No/No Abs/Abs*	No/Yes Abs/Pres	Yes/No Pres/Abs	Yes/Yes Pres/Pres		
OTV (n=217)	Increased maximal dimension of erythema >25%	196	4	1	16	98%	0.85
	Worsened swelling and tenderness	199	2	4	12	97%	0.79
EOT (n=157)	No improvement erythema	154	0	3	0	98%	0.00 - N/A
	No improvement swelling and tenderness**	153	0	2	1	99%	0.50
TOC (n=171)	More than minimal erythema	160	2	7	2	95%	0.28
	More than minimal swelling	160	1	7	3	95%	0.41
	More than minimal tenderness	165	1	2	3	98%	0.66

Abs = Absent or minimal; Pres = Present; OTV = on-therapy (Days 2-3); EOT = end-of-therapy (Days 7-10); TOC = test-of-cure (Days 14-21)

*Number of participants that were assessed by two observers who indicated presence or absence of characteristics defining clinical failure.

** One observer did not provide response to whether there was improvement in swelling and tenderness, so total number of observer responses presented are only 156, not 157.

eTable 2. Secondary Outcomes Among Participants With Cellulitis Treated With Cephalexin Plus Trimethoprim-Sulfamethoxazole or Cephalexin Plus Placebo in the Per Protocol Population

Outcome	**Visit***	**Response by Treatment Group**		**Difference in Response Rates Between Treatment Groups**	**95% Confidence Interval of the Difference in Response Rates**
		Cephalexin plus Trimethoprim-Sulfamethoxazole n=218	**Cephalexin plus Placebo n=193**		
Composite clinical cure[†] - n (%)	TOC	160 (73.4)	149 (77.2)	-3.8	-12.6, 5.0
Surgical procedure – n (%)	TOC	26 (11.9)	17 (8.8)	3.1	-3.2, 9.5
	EFU	33 (15.1)	20 (10.4)	4.8	-2.1, 11.7
Hospitalization - n (%)	TOC	17 (7.8)	10 (5.2)	2.6	-2.6, 7.8
Recurrent skin infection at original site - n (%)	TOC	30 (13.8)	22 (11.4)	2.4	-4.5,9.3
	EFU	33 (15.1)	24 (12.4)	2.7	-4.4, 9.9
New skin infection (at a different site) - n(%)	TOC	6 (2.8)	11 (5.7)	-2.9	-7.4, 1.5
	EFU	13 (6.0)	18 (9.3)	-3.4	-9.0, 2.3
Similar infection in household member - n(%)	TOC	6 (2.8)	4 (2.1)	0.7	-2.8, 4.1
	EFU	10 (4.6)	5 (2.6)	2.0	-2.1, 6.1
Presence of swelling/induration - n(%)	OT	110/217 (50.7)	101/192 (52.6)	-1.9	-12.1. 8.3
	EOT	29/213 (13.6)	31/190 (16.3)	-2.7	-10.2, 4.8
	TOC	9/215 (4.2)	5/192 (2.6)	1.6	-2.4, 5.6

eTable 2. Secondary Outcomes Among Participants With Cellulitis Treated With Cephalexin Plus Trimethoprim-Sulfamethoxazole or Cephalexin Plus Placebo in the Per Protocol Population (continued)

Outcome	Visit*	Response by Treatment Group		Difference in Response Rates Between Treatment Groups	95% Confidence Interval of the Difference in Response Rates
		Cephalexin plus Trimethoprim-Sulfamethoxazole n=218	Cephalexin plus Placebo n=193		
Presence of tenderness - n(%)	OT	90/217 (41.5)	83/192 (43.2)	-1.8	-11.8, 8.3
	EOT	18/195 (8.5)	17/190 (8.9)	-0.5	-6.5, 5.5
	TOC	7/215 (3.3)	4/192 (2.1)	1.2	-2.4, 4.8
Median change in area of erythema[§] from baseline, cm (IQR)[¶]	OT	53.0 (11.9-164.9)	47.1 (11.0-112.7)	5.9	-4.8, 29.4[**]
	EOT	102.1 (33.3-233.5)	94.2 (31.4-164.9)	7.9	-6.3, 31.1[**]
	TOC	102.1 (37.7-274.9)	96.6 (37.3-172.8)	5.5	-6.7, 29.9[**]
Median Days missed from Normal Activities (IQR)[¶]	NA	1.0 (0.0-3.0)	1.0 (0.0-3.0)	0.0	0.0, 0.0[**]
Median Days missed from work/school (IQR)[¶]	NA	1.0 (0.0-3.0)	1.0 (0.0-3.0)	0.0	0.0, 0.0[**]
Median Days of analgesic use (IQR)[¶]	NA	3.0 (0.0-8.0)	2.0 (0.0-8.0)	1.0	0.0, 1.0[**]

[*] Through follow-up visits: OT = on-therapy (3-4 days of treatment); TOC = test-of-cure (7-14 days after the end of a seven-day treatment); EFU = extended follow-up (42-56 days after the end of a seven-day treatment)
[†] Composite clinical cure = resolution of all symptoms and signs of infection, or improvement to such an extent that no additional antibiotic therapy and/or surgical procedures were necessary.
[‡] Denominators are presented for variables with missing data.
[§] Area of erythema is calculated by 1/4x pi x Length x Width. Change in Area is calculated as Baseline - Visit.
[‖] IQR=Interquartile range
[¶] Data are based on participant reports in the first 14 days.
[**] Hodges-Lehmann asymptotic confidence intervals for estimation of location shifts.

eTable 3. Summary of Adverse Events by Severity and Relationship to Treatment Among Safety Population

Treatment Group=TMP/SMX + Cephalexin (N=248)								
				Severity of AEs among those who experienced an AE*				
Relatedness	Total No. of AEs	No. (%) of participants experiencing an AE **	No. (%) of participants with a Serious AE*	No. (%) of participants with a Mild AE	No. (%) of participants with a Moderate AE	No. (%) of participants with a Severe AE	No. (%) of participants with a Life-Threatening AE	Total No. (%) of Deaths
Yes	168	102 (41.1)	1 (0.5)	90 (48.4)	25 (13.4)	1 (0.5)	-	-
No	300	146 (58.9)	19 (10.2)	116 (62.4)	65 (34.9)	11 (5.9)	1 (0.5)	-
Total	468	186 (75.0)	20 (10.8)	165 (88.7)	81 (43.5)	12 (6.5)	1 (0.5)	-

Treatment Group=Cephalexin Alone (N=248)								
				Severity of AEs among those who experienced an AE*				
Relatedness	Total No. of AEs	No. (%) of participants experiencing an AE **	No. (%) of participants with a Serious AE*	No. (%) of participants with a Mild AE	No. (%) of participants with a Moderate AE	No. (%) of participants with a Severe AE	No. (%) of participants with a Life-Threatening AE	Total No. (%) of Deaths
Yes	142	90 (36.3)	-	81 (44.5)	18 (9.9)	-	-	-
No	313	158 (63.7)	21 (11.5)	135 (74.2)	55 (30.2)	11 (6.0)	-	1 (0.5)
Total	455	182 (73.4)	21 (11.5)	163 (89.6)	68 (37.4)	11 (6.0)	-	1 (0.5)

* Denominator for percentages is the number of participants with an adverse event for each treatment group, i.e.,186 for TMP/SMX + Cephalexin and 182 for Cephalexin Alone.
** Denominator for percentages is the number of participants in the safety population for each treatment group, i.e., 248 in both groups

eTable 4. Summary of Adverse Events (AE) Among Safety Population by Treatment Group

	TMP/SMX+Cephalexin (N=248)	Cephalexin (N=248)
MedDRA System Organ Class*/Preferred Term	**Participants Experiencing AEs N(%)****	**Participants Experiencing AEs N(%)****
Blood and lymphatic system disorders	0 (0.0)	3 (1.2)
Lymph node pain	0 (0.0)	1 (0.4)
Microcytic anemia	0 (0.0)	1 (0.4)
Thrombocytopenia	0 (0.0)	1 (0.4)
Cardiac disorders	0 (0.0)	1 (0.4)
Bradycardia	0 (0.0)	1 (0.4)
Eye disorders	1 (0.4)	0 (0.0)
Vision blurred	1 (0.4)	0 (0.0)
Gastrointestinal disorders	114 (46.0)	96 (38.7)
Abdominal discomfort	1 (0.4)	4 (1.6)
Abdominal pain	8 (3.2)	7 (2.8)
Abdominal pain upper	19 (7.7)	11 (4.4)
Constipation	7 (2.8)	5 (2.0)
Diarrhea	54 (21.8)	47 (19.0)
Dry mouth	1 (0.4)	0 (0.0)
Duodenal ulcer	0 (0.0)	1 (0.4)
Dyspepsia	2 (0.8)	0 (0.0)
Dysphagia	0 (0.0)	1 (0.4)
Flatulence	2 (0.8)	3 (1.2)
Inguinal hernia	1 (0.4)	0 (0.0)
Lip blister	0 (0.0)	1 (0.4)
Nausea	49 (19.8)	41 (16.5)
Esophageal achalasia	0 (0.0)	1 (0.4)
Toothache	1 (0.4)	1 (0.4)
Vomiting	19 (7.7)	19 (7.7)
General disorders and administration site conditions	31 (12.5)	34 (13.7)
Adverse drug reaction	0 (0.0)	1 (0.4)
Asthenia	1 (0.4)	1 (0.4)
Chest discomfort	0 (0.0)	1 (0.4)

eTable 4. Summary of Adverse Events (AE) Among Safety Population by Treatment Group (continued)

	TMP/SMX+Cephalexin (N=248)	Cephalexin (N=248)
MedDRA System Organ Class*/Preferred Term	**Participants Experiencing AEs N(%)****	**Participants Experiencing AEs N(%)****
Chest pain	2 (0.8)	3 (1.2)
Chills	2 (0.8)	2 (0.8)
Fatigue	6 (2.4)	7 (2.8)
Induration	1 (0.4)	1 (0.4)
Inflammation	1 (0.4)	0 (0.0)
Influenza like illness	1 (0.4)	0 (0.0)
Injury associated with device	1 (0.4)	0 (0.0)
Local swelling	0 (0.0)	2 (0.8)
Nodule	2 (0.8)	1 (0.4)
Edema peripheral	2 (0.8)	0 (0.0)
Pain	1 (0.4)	1 (0.4)
Pyrexia	13 (5.2)	15 (6.0)
Swelling	0 (0.0)	4 (1.6)
Hepatobiliary disorders	0 (0.0)	1 (0.4)
Cholelithiasis	0 (0.0)	1 (0.4)
Immune system disorders	0 (0.0)	1 (0.4)
Hypersensitivity	0 (0.0)	1 (0.4)
Infections and infestations	71 (28.6)	89 (35.9)
Abscess	30 (12.1)	37 (14.9)
Abscess limb	1 (0.4)	1 (0.4)
Bronchitis	1 (0.4)	0 (0.0)
Bursitis infective	0 (0.0)	1 (0.4)
Cellulitis	33 (13.3)	39 (15.7)
Clostridium difficile colitis	1 (0.4)	0 (0.0)
Diverticulitis	1 (0.4)	0 (0.0)
Folliculitis	0 (0.0)	4 (1.6)
Fungal infection	1 (0.4)	1 (0.4)
Groin abscess	1 (0.4)	1 (0.4)
Influenza	2 (0.8)	2 (0.8)

eTable 4. Summary of Adverse Events (AE) Among Safety Population by Treatment Group (continued)

	TMP/SMX+Cephalexin (N=248)	Cephalexin (N=248)
MedDRA System Organ Class*/Preferred Term	**Participants Experiencing AEs N(%)****	**Participants Experiencing AEs N(%)****
Nasopharyngitis	4 (1.6)	8 (3.2)
Necrotizing fasciitis	1 (0.4)	0 (0.0)
Oral herpes	2 (0.8)	0 (0.0)
Osteomyelitis	1 (0.4)	0 (0.0)
Paronychia	0 (0.0)	1 (0.4)
Pelvic inflammatory disease	0 (0.0)	1 (0.4)
Periorbital cellulitis	1 (0.4)	1 (0.4)
Pyelonephritis	0 (0.0)	1 (0.4)
Rash pustular	1 (0.4)	4 (1.6)
Salmonellosis	1 (0.4)	0 (0.0)
Subcutaneous abscess	1 (0.4)	1 (0.4)
Tinea infection	0 (0.0)	1 (0.4)
Tinea pedis	2 (0.8)	0 (0.0)
Urinary tract infection	2 (0.8)	0 (0.0)
Wound abscess	1 (0.4)	0 (0.0)
Wound infection	0 (0.0)	1 (0.4)
Injury, poisoning and procedural complications	14 (5.6)	13 (5.2)
Alcohol poisoning	0 (0.0)	1 (0.4)
Arthropod bite	0 (0.0)	2 (0.8)
Arthropod sting	1 (0.4)	0 (0.0)
Contusion	2 (0.8)	0 (0.0)
Excoriation	3 (1.2)	1 (0.4)
Laceration	1 (0.4)	2 (0.8)
Limb injury	0 (0.0)	1 (0.4)
Muscle strain	1 (0.4)	0 (0.0)
Post procedural complication	1 (0.4)	0 (0.0)
Road traffic accident	0 (0.0)	1 (0.4)
Sunburn	1 (0.4)	1 (0.4)
Tendonitis	1 (0.4)	0 (0.0)

eTable 4. Summary of Adverse Events (AE) Among Safety Population by Treatment Group (continued)

	TMP/SMX+Cephalexin (N=248)	Cephalexin (N=248)
MedDRA System Organ Class*/Preferred Term	**Participants Experiencing AEs N(%)****	**Participants Experiencing AEs N(%)****
Thermal burn	2 (0.8)	2 (0.8)
Wound	2 (0.8)	1 (0.4)
Wound complication	0 (0.0)	1 (0.4)
Metabolism and nutrition disorders	6 (2.4)	3 (1.2)
Decreased appetite	3 (1.2)	3 (1.2)
Dehydration	1 (0.4)	0 (0.0)
Hyperglycemia	1 (0.4)	0 (0.0)
Hypokalemia	1 (0.4)	0 (0.0)
Impaired fasting glucose	1 (0.4)	0 (0.0)
Metabolic alkalosis	1 (0.4)	0 (0.0)
Musculoskeletal and connective tissue disorders	14 (5.6)	11 (4.4)
Achilles tendon discomfort	1 (0.4)	0 (0.0)
Arthralgia	0 (0.0)	1 (0.4)
Back pain	2 (0.8)	3 (1.2)
Bursitis	0 (0.0)	1 (0.4)
Flank pain	1 (0.4)	0 (0.0)
Limb discomfort	1 (0.4)	0 (0.0)
Muscle spasms	1 (0.4)	1 (0.4)
Musculoskeletal pain	0 (0.0)	1 (0.4)
Musculoskeletal stiffness	1 (0.4)	0 (0.0)
Myalgia	2 (0.8)	1 (0.4)
Neck pain	0 (0.0)	1 (0.4)
Pain in extremity	6 (2.4)	2 (0.8)
Nervous system disorders	57 (23.0)	52 (21.0)
Burning sensation	0 (0.0)	1 (0.4)
Dizziness	18 (7.3)	16 (6.5)
Headache	41 (16.5)	42 (16.9)
Lethargy	0 (0.0)	1 (0.4)
Migraine	1 (0.4)	0 (0.0)

eTable 4. Summary of Adverse Events (AE) Among Safety Population by Treatment Group (continued)

	TMP/SMX+Cephalexin (N=248)	Cephalexin (N=248)
MedDRA System Organ Class*/Preferred Term	**Participants Experiencing AEs N(%)****	**Participants Experiencing AEs N(%)****
Neuralgia	1 (0.4)	0 (0.0)
Somnolence	4 (1.6)	1 (0.4)
Tremor	1 (0.4)	0 (0.0)
Psychiatric disorders	1 (0.4)	2 (0.8)
Anxiety	1 (0.4)	0 (0.0)
Insomnia	0 (0.0)	1 (0.4)
Mental disorder	0 (0.0)	1 (0.4)
Renal and urinary disorders	2 (0.8)	3 (1.2)
Dysuria	0 (0.0)	1 (0.4)
Urinary frequency	1 (0.4)	1 (0.4)
Renal failure	0 (0.0)	1 (0.4)
Renal failure acute	1 (0.4)	0 (0.0)
Reproductive system and breast disorders	2 (0.8)	2 (0.8)
Penile vein thrombosis	0 (0.0)	1 (0.4)
Pruritus genital	0 (0.0)	1 (0.4)
Testicular pain	1 (0.4)	0 (0.0)
Vulvovaginal pruritus	1 (0.4)	0 (0.0)
Respiratory, thoracic and mediastinal disorders	7 (2.8)	11 (4.4)
Asthma	0 (0.0)	1 (0.4)
Cough	4 (1.6)	5 (2.0)
Dry throat	0 (0.0)	1 (0.4)
Epistaxis	2 (0.8)	0 (0.0)
Musculoskeletal chest pain	0 (0.0)	1 (0.4)
Nasal congestion	1 (0.4)	0 (0.0)
Oropharyngeal pain	0 (0.0)	3 (1.2)
Sinus congestion	1 (0.4)	0 (0.0)
Skin and subcutaneous tissue disorders	30 (12.1)	27 (10.9)
Acne	0 (0.0)	1 (0.4)
Angioedema	0 (0.0)	1 (0.4)

eTable 4. Summary of Adverse Events (AE) Among Safety Population by Treatment Group (continued)

	TMP/SMX+Cephalexin (N=248)	Cephalexin (N=248)
MedDRA System Organ Class*/Preferred Term	**Participants Experiencing AEs N(%)****	**Participants Experiencing AEs N(%)****
Blister	2 (0.8)	3 (1.2)
Dermatitis contact	1 (0.4)	0 (0.0)
Dry skin	1 (0.4)	2 (0.8)
Ecchymosis	2 (0.8)	0 (0.0)
Erythema	1 (0.4)	4 (1.6)
Hyperhidrosis	1 (0.4)	0 (0.0)
Night sweats	1 (0.4)	1 (0.4)
Pruritus	5 (2.0)	10 (4.0)
Pruritus generalized	1 (0.4)	0 (0.0)
Rash	14 (5.6)	5 (2.0)
Rash generalized	0 (0.0)	1 (0.4)
Rash pruritic	0 (0.0)	1 (0.4)
Skin exfoliation	0 (0.0)	1 (0.4)
Skin irritation	0 (0.0)	1 (0.4)
Skin ulcer	1 (0.4)	0 (0.0)
Swelling face	1 (0.4)	0 (0.0)
Urticaria	3 (1.2)	1 (0.4)
Vascular disorders	7 (2.8)	3 (1.2)
Deep vein thrombosis	1 (0.4)	0 (0.0)
Hematoma	1 (0.4)	0 (0.0)
Hypertension	3 (1.2)	2 (0.8)
Hypertensive crisis	1 (0.4)	0 (0.0)
Hypotension	1 (0.4)	0 (0.0)
Phlebitis	0 (0.0)	1 (0.4)
Total	186 (75.0)	182 (73.4)

TMP/SMX = Trimethoprim-sulfamethoxazole
* Version 17.0 of the Medical Dictionary for Regulatory Activities
** Denominator for percentages is the number of participants in the safety population.