A Randomized Multicenter Study for Isolated Skin Vasculitis

NCT02939573

Status	RECRUITING
Phase	Phase 2
Sponsor	University of Pennsylvania
Enrollment	90 participants

Key Eligibility Criteria

Inclusion (10)

• Patients with primary skin vasculitis, not associated with any significant extra-cutaneous involvement that would require specific immunosuppressive therapy. Eligible patients will have a diagnosis of either:

• Isolated cutaneous small vessel (SV) or medium-sized vessel (MV) vasculitis or cutaneous polyarteritis nodosa (PAN)

• IgA vasculitis (IgA, formerly Henoch-Schönlein purpura), without active and/or progressing renal involvement (stable glomerular filtration rate (GFR) \>60 ml/min; absence of, or mild-and-stable microscopic hematuria without red blood cell casts; absence of, or mild-and-stable proteinuria (\<1g/24 hours); not requiring systemic immunosuppressive therapy).

• These conditions, when skin-limited, are all currently treated in similar manners in practice. Mild arthralgias, myalgias, peripheral limb edema, fatigue, weight loss d6 lbs or 3 kg within past 3 months, low-grade fever, and mild anemia (Hb e 10 g/dL) will be allowed.

• The diagnosis of vasculitis must have been confirmed by skin biopsy prior to enrollment (earlier, at diagnosis, and/or just prior to enrollment) that has included an immunofluorescence study (in the case of small vessel vasculitis).

... and 5 more (see full listing online)

Exclusion (14)

• Known systemic and/or non-skin-isolated vasculitis, such as granulomatosis with polyangiitis, eosinophilic granulomatosis with polyangiitis, cryoglobulinemic vasculitis, systemic polyarteritis nodosa, central nervous system vasculitis and patients with detectable antineutrophil cytoplasmic antibody (ANCA) by immunofluorescence or ELISA.

• Hypocomplementemic urticarial vasculitis, cryoglobulinemic vasculitis, and other known secondary skin vasculitides such as those secondary to systemic lupus erythematosus, Sjögren syndrome, another auto-immune condition, a cancer, a hematological disorder, an ongoing active infection, or an ongoing medication. Investigators should consider such underlying diagnoses and perform and interpret appropriate laboratory work-up where indicated based on clinical presentation.

• History of significant intolerance, allergy or serious adverse events to any of the study medications: such patients can be enrolled directly in the second stage of the study and be randomized to receive one of the two other study drugs. The number of patients enrolled directly in stage 2 of the study will be capped at 10 (10%).

• Patients who have contra-indications to two or three of the study drugs (azathioprine, colchicine, or dapsone), or have been treated prior to enrollment with two or three of the study drugs but failed to respond to them, or had to stop two or three of them because of adverse events.

• Deficit in glucose-6-phosphate dehydrogenase (G6PD) or history of hemolytic anemia (all patients must be tested for G6PD at the screening visit to assess for their eligibility): such patients can be enrolled directly in the second stage of the study and be randomized to receive one of the two other study drugs (azathioprine or colchicine). The number of patients enrolled directly in stage 2 of the study will be capped at 10 (10%).

... and 9 more (see full listing online)

Locations (16 total)

University of Kansas Medical Center, Kansas City, Kansas, United States
Boston University School of Medicine, Boston, Massachusetts, United States
Mayo Clinic, Rochester, Minnesota, United States
... and 13 more locations

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