ARAMIS

A randomized multicenter study for isolated skin vasculitis

Sponsor: Vasculitis Clinical Research Consortium (VCRC)
Mount Sinai Hospital - Site Activation: Sept. 2017
Site Primary Investigator: Dr. Christian Pagnoux (christian.pagnoux@sinaihealthsystem.ca)
Site Sub-Investigator: Dr. Simon Carette (simon.carette@uhn.ca)
Study Coordinator: Vendramini, Judy (Judy.Vendramini@sinaihealthsystem.ca)

Objective and Background:
To evaluate the efficacy of 3 different standard of care medications (Colchicine, Dapsone, Azathioprine) in the treatment of isolated skin vasculitis

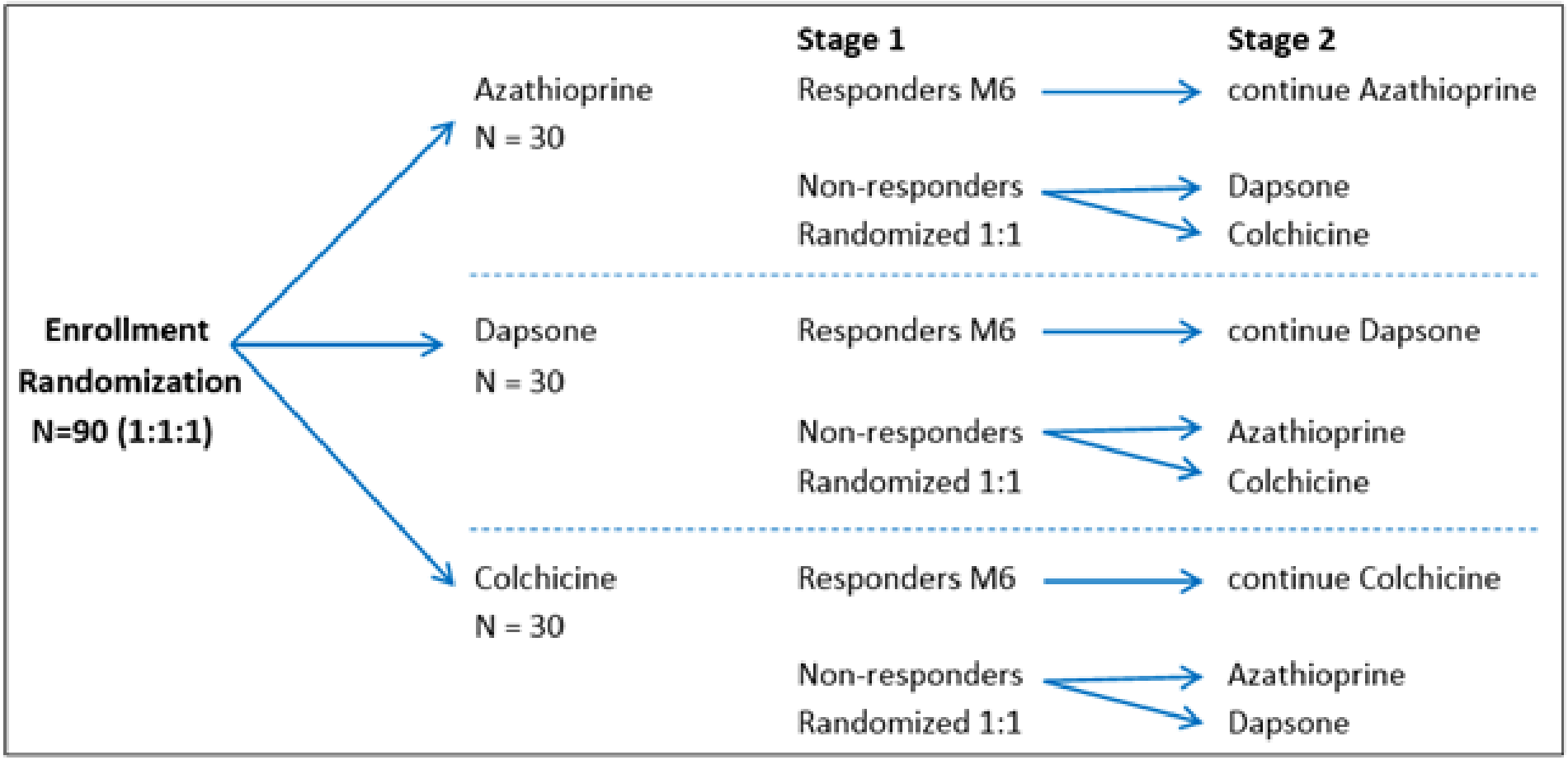
Study Design:
- Multiple assignment randomized trial
- Enrolled subjects will be randomized in a 1:1:1 ratio to receive either colchicine 0.6mg x 2/day or dapsone 150mg/day or azathioprine 2mg/kg/day for 6 months (stage 1)
- Patients with contraindication or who failed to respond to one of the study drugs can be randomized to receive one of the other two study drugs (stage 2)
- Patients on prednisone at enrollment will be tapered off within 6 weeks of enrollment. If taking low dose for other reason than vasculitis treatment (≤ 5mg/day), patients can remain on this dose during study period
- Endpoint is the proportion of patients achieving response to therapy at month 6 (stages 1 or 2)

Needed number of patients to enroll:
Approximately 90 patients will be enrolled

For more information on the study or enrollment procedure, please contact study site PI, sub-I or study coordinator using emails above, or by phone at 416-586-4800 ext. 8549 or 5519 or 2210

Inclusion Criteria:
1. Age ≥ 18 years
2. Patients with primary skin vasculitis, either:
   a. Isolated cutaneous small vessel (SV) or medium-sized vessel (MV) vasculitis or cutaneous polyarteritis nodosa (PAN)
   b. IgA vasculitis, without active and/or progressing renal involvement (stable GFR>60ml/min; absence/mild and stable microscopic hematuria without RBC casts; absence/mild and stable proteinuria <1g/24hours; not requiring systemic immunosuppressive therapy)
3. Vasculitis diagnosis confirmed by skin biopsy prior to enrollment with immunofluorescence study (for SV vasculitis)
4. Active cutaneous vasculitis for at least 1 month continuously and/or ≥2 flares over 6 months prior to enrollment
5. Active/ongoing cutaneous vasculitis lesions at time of enrollment

Exclusion criteria:
1. Presence of significant extra-cutaneous manifestations suggestive of systemic vasculitis or more diffuse condition, including systemic and/or non-skin isolated vasculitis
2. Contraindications or failure to respond in the past to two or three of the study drugs
3. Significant hepatic or renal insufficiency
4. Comorbid conditions requiring intermittent courses of prednisone during study period
5. Active cancer/history of malignancy within previous 5 years
6. Pregnant/lactating women


Stage 1
Stage 2
Enrollment
Randomization
N=90 (1:1:1)
Azathioprine
N = 30
Responders M6
continue Azathioprine
Non-responders
Randomized 1:1
Dapsone
Colchicine
Dapsone
N = 30
Responders M6
continue Dapsone
Non-responders
Randomized 1:1
Azathioprine
Colchicine
Colchicine
N = 30
Responders M6
continue Colchicine
Non-responders
Randomized 1:1
Azathioprine
Dapsone