TAPIR

The Assessment of Prednisone In Remission Trial (TAPIR) – Centers of Excellence Approach

Sponsor: Vasculitis Clinical Research Consortium (VCRC)

Mount Sinai – Site Activation: February 2014
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Objectives and Background:
To study the effects (at 6 months) of continuing low-dose glucocorticoids vs. stopping glucocorticoid treatment entirely in patients with granulomatosis with polyangiitis (GPA)

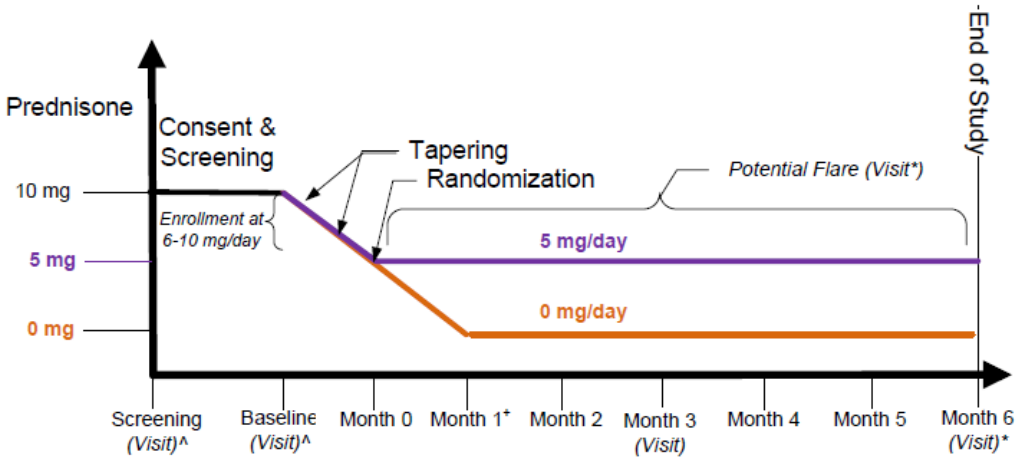
Study Design:
- Open label multi-center study
- Eligible patients are those patients who had active GPA in the last 12 months and are now in remission, taking prednisone at doses between 6 mg/day and 10 mg/day
- Eligible patients will then taper their prednisone to 5mg/day and be randomized to continue prednisone at 5 mg/day or taper it gradually to 0 mg/day
- Patients will be followed for 6 months (screening, baseline, M3 and M6 visits)
- Endpoint is the number of patients for whom the physician will decide to increase glucocorticoids for disease relapse

Needed number of patients to enroll:
60 patients
Primary hypothesis is a difference of ≥30% in the relapse rate.
With a randomization ratio of 1:1, a 80% power, a 2-tailed significance level of 0.05, and assuming a maximum 20% drop out, 120 participants are needed (60 per arm, with 60 accrued through this "Center of excellence" protocol and 60 from a complementary study, that recruits through social media/FP)

Inclusion Criteria:
1. Age ≥ 18 years
2. Newly-diagnosed or relapsing GPA, with ≥ 2/5 modified ACR criteria (including *d* OR *e*):
   a. *Nasal/oral inflammation (oral ulcers, bloody nasal discharge)*
   b. *Abnormal chest radiograph*
   c. *Active urinary sediment (>5 RBC) or RBC casts*
   d. *Granulomatosis inflammation on biopsy*
   e. *Positive ANCA test*
3. Active disease within the last 12 months, that needed > 20 mg/d prednisone
4. In remission and on prednisone 6 mg/day to 10 mg/day at time of enrollment
5. If on AZA, LEF, 6-MP, MTX, MMF, cotrimoxazole: the dose must be stable for 1 month prior to study and for the duration of the study; RTX is acceptable as long as the last dose was given at least 1 month prior to enrollment

Exclusion Criteria:
- Comorbid condition(s) that has/have a moderate likelihood of requiring prednisone within one year of enrollment (COPD, asthma etc)

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



^The Screening and Baseline visits may be combined into 1 visit
*Visit will take place either at the first incidence of a flare or at Month 6
+At month 1, Coordinator will call subject to confirm prednisone dose

Time point									
Enrollment	Starting Dose mg/day								
	10		9		8		7		6	
Day 1	9		8		7		6		5 Randomization	
									5mg/day	0mg/day
Week 1	8		7		6		5 Randomization		5	4
							5mg/day	0mg/day		
Week 2	7		6		5 Randomization		5	4	5	3
					5mg/day	0mg/day				
Week 3	6		5 Randomization		5	4	5	3	5	2
			5mg/day	0mg/day						
Week 4	5 Randomization		5	4	5	3	5	2	5	1
	5mg/day	0mg/day								
Week 5	5	4	5	3	5	2	5	1	5	0
Week 6	5	3	5	2	5	1	5	0	5	0
Week 7	5	2	5	1	5	0	5	0	5	0
Week 8	5	1	5	0	5	0	5	0	5	0
Week 9	5	0	5	0	5	0	5	0	5	0
Week 10-End of Study	5	0	5	0	5	0	5	0	5	0