TAPIR

THE ASSESSMENT OF PREDNISONE IN REMISSION TRIAL

A new approach to conducting randomized clinical trials
in the community setting.

IRB # Pro00013241

The TAPIR trial is sponsored by:

VASCULITIS CLINICAL RESEARCH CONSORTIUM

Vasculitis Clinical Research Consortium (VCRC)

National Heart Lung and Blood Institute (NHLBI)

National Institutes of Health

Quick Facts

- This trial is a new approach to conducting a randomized clinical trial in the community setting.
- Your patient remains under your care.
- Participants will be randomized to a dose of 5mg or 0mg of prednisone daily. You as this patient's treating physician may modify their prednisone dose at any time during the trial.
- Participants are ineligible if the randomized dose does not meet your standard of care.
- Participants may participate for a maximum of 6 months.
- You do not need IRB approval.

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WHO WE ARE: THE STUDY TEAM

VASCULITIS CLINICAL RESEARCH CONSORTIUM

- The VCRC (www.RDCRN.org/vasculitis) is the major clinical research infrastructure in North America for the study of vasculitis.
- The VCRC includes 11 major vasculitis clinical centers in the US and Canada and dozens more partner sites in the US, Europe, Asia, and Australia.

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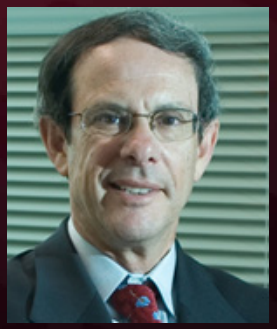
University of Pennsylvania

Professor and Chief of the Division of Rheumatology, Department of Medicine, University of Pennsylvania School of Medicine.



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RATIONALE:
Why we are doing this trial

- Optimal treatment strategies for GPA remain to be defined.

> ? Are patients with GPA better off being maintained on low-dose prednisone or attempting to come off of prednisone altogether?

- We are testing a new trial approach: let patients participate from any location (within the United States). Proximity to trial site and travel are not required.
- We are measuring the effectiveness of recruiting patients through social media.

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Is Your Patient Eligible

Eligible patients will have:	Patients will be **ineligible** if they have:
• An established diagnosis of granulomatosis with polyangiitis (GPA) per the modified 1990 ACR classification criteria • Disease remission at time of enrollment • Active disease within the prior 12 months (initial presentation or relapse) • At the time of active disease required treatment with prednisone ≥20 mg/day • Prednisone dose at time of enrollment between 5 and 20 mg/day. Please note that participants may be on other medications for the control of their GPA disease besides prednisone and still participate in this trial • An age of 18 years or greater • Agreement from their Community Physician that randomized treatment assignment is standard of care (reasonable for treatment of their disease)	• Have comorbid condition that has moderate likelihood of requiring a course of prednisone within one year of enrollment (e.g. COPD, asthma, adrenal insufficiency)

No patient may participate in the TAPIR trial without agreement from their local physician that the trial dose is in accordance with his or her physician's own standard of care

YOUR INVOLVEMENT:
What is expected of local physicians

1. Your patient will provide you with a *Physicians Packet* which will include:

- Description of this trial
- Form for you to sign and indicate whether you agree that either 5 mg or 0 mg per day of prednisone is appropriate treatment for your patient
- Signed medical release form from the patient

2. If you agree either 5m or 0 mg per day of prednisone is appropriate for your patient, fax or email *Physicians Packet* & requested medical records to (813) 910-1269.

Endpoint:
6
MONTHS

3. Continue to provide care for your patient as you normally would.*

*Please note: You as this patient's physician may modify your patient's prednisone dose as clinically indicated during this trial.

TAPIR Trial Timeline

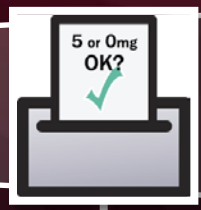
1. Patient with GPA is recruited via support networks & social media.

2. Patient enrolls & consents online through the TAPIR website: www.TAPIRTrial.org

3. The participant gives *Physician Packet* & signed medical release form to their treating physician.

4. If physician agrees that a dose of 5 mg or 0 mg prednisone is appropriate treatment, the patient becomes eligible for the trial.

Physician returns *Physician Packet* & requested medical records to TAPIR Trial Team.



5. Physician tapers patient's prednisone down to 5 mg daily.

Once patient enters 5 mg on their daily prednisone diary, they will receive their randomized trial dose.

6. Participant records their dose online daily & periodically asked to complete questionnaires.

7. Participant takes trial dose for 6 months or until otherwise directed by their physician.

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Online Resources

Contact us

If you have any questions please contact the TAPIR trial coordinator at TAPIR@epi.usf.edu or 1-888-443-1793.

Resources

- Full Study Summary
- View Informed Consent
- 1990 ACR classification criteria.
- MICHAEL WALSH, PETER A. MERKEL, ALFRED MAHR, AND DAVID JAYNE. Effects of Duration of Glucocorticoid Therapy on Relapse Rate in Antineutrophil Cyto plasmic Antibody–Associated Vasculitis: A Meta-Analysis. Arthritis Care & Research, Vol. 62, No. 8, August 2010, pp 1166–1173.

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