DGIM Project Summary

(1 page preferred, 2 pages maximum)

Name of Project: Nonalcoholic Fatty Liver Disease & Polycystic Ovary Syndrome

Investigator(s). (Include phone numbers and email address, indicate PI and primary contact)
PI: Monika Sarkar, MD | monika.sarkar@ucsf.edu
Study coordinator (primary contact): Tab Srisengfa | tab.srisengfa@ucsf.edu

Research question(s):
What is the prevalence and severity of nonalcoholic fatty liver disease in women with polycystic ovarian syndrome and obesity?

Brief Background/Significance:
Nonalcoholic fatty liver disease (NAFLD) is the most common liver condition in the United States, affecting 25-30% of all Americans. Retrospective studies have shown a high prevalence of NAFLD in women with polycystic ovary syndrome (PCOS) which may relate to their metabolic risk factors and high testosterone levels. To date there are no standardized screening recommendations for NAFLD in PCOS and whether obese women with PCOS have evidence of severe steatosis or fibrosis is not known. In this study we aim to perform a painless, 20-minute, ultrasound-based imaging test call transient-elastrography (TE) with controlled attenuation parameter (CAP). TE-CAP is approved by the FDA for assessment of hepatic steatosis and fibrosis.

Inclusion/exclusion criteria (list)
Inclusion: Women aged 18-45 years with Polycystic Ovary Syndrome (PCOS) who are overweight or obese or have known fatty liver disease
Exclusion: Pregnant or nursing women

Method of contact/recruitment (be specific)
Fliers will be posted at the clinic, and there will be contact information pull-off tabs for patients who are interested in the study. Patients will initiate contact with us if they are interested in our study.

Benefits/burden for participants (clearly identify potential for harm)
The benefits of this test are that patients will learn about their liver health and have the opportunity to speak to a hepatologist about these findings. If interested, they will also learn about other clinical trials available for treating NAFLD. Burden to patients includes traveling to the Parnassus campus, although parking will be reimbursed. There is no discomfort, pain, or radiation exposure with TE-CAP and the test takes about 15-20 minutes.

Any benefits or burden to DGIM practitioners?
There is no burden to DGIM practitioners. A benefit is that practitioners will have access to test results which can help inform patients care.

Timeline for recruitment (projected start and stop dates)
March 2019 to March 2020

Funding source
K23 Grant, UCSF GI/Hepatology Division Support, and Zydus Pharmaceuticals

Potential for DGIM collaborators? (We encourage DGIM resident and fellow involvement in particular)
Yes- DGIM residents or fellows who are interested in collaborating on research in liver disease in women are encouraged to contact Dr.Sarkar for study involvement.

Do you agree to notify us when recruitment is completed?
Yes

Date form completed: 27-Feb-2019