CLINICAL RESEARCH ALLIANCE
newsletter

CROHN'S & COLITIS FOUNDATION OF AMERICA

Clinical Research Alliance Meeting

Monday, May 5, 2014
11.30AM-1.45 PM
Hilton Hotel
720 South Michigan Avenue
Boulevard Room A

11:30 Room open

12:15 Status of the CRA
(H. Herfarth, P. Higgins)

Update of CRA Studies

12:25 MERIT-UC (H. Herfarth)

12:40 PUCCINI (B. Cohen, B. Sands)

12:55 PIANO (U. Mahadevan)

1:10 MARQUEE (M. Osterman)

Presentation of the new CRA study

1:15 High Dose Vitamin D Therapy for Crohn's Disease
(S. Govani, P. Higgins)

CRA Topic

1:25 Universal Contract
(T. Kamphaus, H. Herfarth, P. Higgins, J. Lewis)

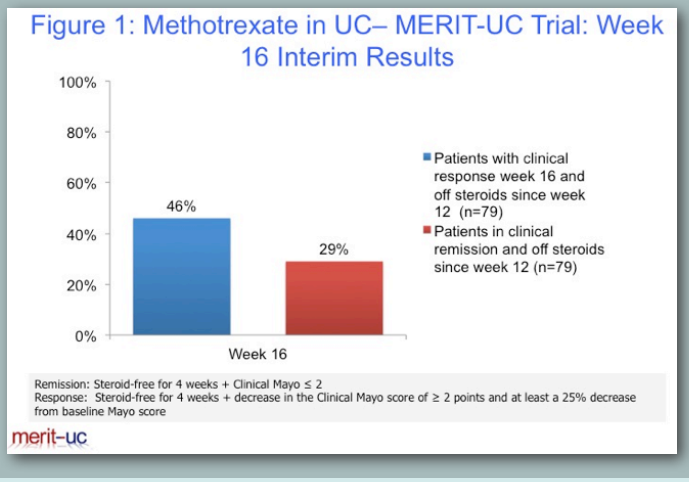
1:45 Adjourn

First Exploratory Analysis of MERIT-UC (MEthotrexate Response In Treatment of UC)
PI: Hans Herfarth, M.D., Ph.D.

So far, we have screened 139 patients for MERIT-UC and included 93 into the study. An interim analysis of the open label induction period was performed in January 2014.

The main outcomes for 76 patients completing the open label induction period of 16 weeks are shown in Figure 1. We observed a 46% clinical response rate at week 16. This is remarkable since this endpoint reflects MTX monotherapy 4 weeks after all steroids are stopped at week 12. The steroid free clinical remission rate in MERIT-UC is currently 29%. These are very encouraging numbers, especially if you put this into context with another UC study with a week 16 endpoint - the recently published SUCCESS trial (Figure 2; Panaccione R et al. Combination Therapy With Infliximab and Azathioprine Is Superior to Monotherapy With Either Agent in Ulcerative Colitis. Gastroenterology 2014;146:392-400). The definitions of the endpoints in both studies slightly differ (see Figure 1 and Figure 2). MERIT-UC also included anti-TNF and azathioprine failures, whereas SUCCESS included only anti-TNF naïve patients and patients who were off azathioprine for 3 months or never exposed to azathioprine.

Overall, the data of the open label induction period suggest that MTX has comparable efficacy to azathioprine or anti-TNF therapy to achieve a steroid free remission.



Chairman Clinical Research Alliance
Hans Herfarth, MD, PhD
hherf@med.unc.edu

Co-Chairman Clinical Research Alliance
Peter Higgins, MD, PhD, MPH
phiggins@med.umich.edu

Director of Collaborative Research Projects, Crohn's and Colitis Foundation of America
Tania Kamphaus, PhD

CRA Administrative Assistant
Susan Jackson, MPA
susan_jackson@med.unc.edu