

CLINICAL RESEARCH ALLIANCE newsletter



CROHN'S & COLITIS
FOUNDATION OF AMERICA

Clinical Research Alliance Meeting

Monday, May 18th, 2015

11:30 AM - 1:45 PM

Mariott Marquis

901 Massachusetts Avenue NW

Washington; District of Columbia

Georgetown University Room

11:30 Lunch

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

Update of CRA Studies

12:25 MERIT-UC (H. Herfarth)

12:35 PUCCINI (B. Cohen, B. Sands)

12:45 PIANO (U. Mahadevan)

12:55 MARQUEE (M. Osterman)

1:05 RODIN - CD (S. Govani)

1:15 Standardized Data Recording Tool
(J. Lewis)

1:25 APRIL (M. Long)

1:35 - 1:45 (A. Weaver, H. Harfarth,
P. Higgins, J. Lewis)

CRA Costs for Trials

CRA Authorship Rules

1:45 Adjourn

PUCCINI—Prospective Cohort of Ulcerative Colitis and Crohn's Disease Patients Undergoing Surgery to Identify Risk Factors for Post-Operative INfection I

PI – Bruce Sands and Ben Cohen

Rationale

Surgery is common in both Crohn's disease (CD) and ulcerative colitis (UC). There is controversy within the literature as to what the risk factors are for post-operative complications in IBD patients. One of the central questions for which the current literature is heterogeneous is whether use of anti-TNF agents peri-operatively poses a risk for infectious and non-infectious complications. The treatment paradigm for both CD and UC has shifted towards early control of disease with immunosuppressive agents, particularly anti-TNF agents. If anti-TNF agents are found to pose a risk for post-operative complications the management of IBD patients in the peri-operative period would need to be changed.

Hypothesis

The primary hypothesis is that peri-operative anti-TNF exposure is an independent risk factor for 30 day incidence of post-operative infection in intra-abdominal surgery for CD and UC

Aims

Aim 1: Determine whether exposure to anti-TNF agents is an independent risk factor for post-operative infection in intra-abdominal surgery for CD and UC

- a. Explore use of peri-operative anti-TNF drug levels as a measure of risk for post-operative infection

Aim 2: Determine whether exposure to anti-TNF agents is an independent risk factor for important non-infectious post-operative outcomes in intra-abdominal surgery for CD and UC such as ileus/small bowel obstruction, thromboembolic event, reoperation, and mortality

- a. Explore use of peri-operative anti-TNF drug levels as a measure of risk for non-infectious post-operative outcomes

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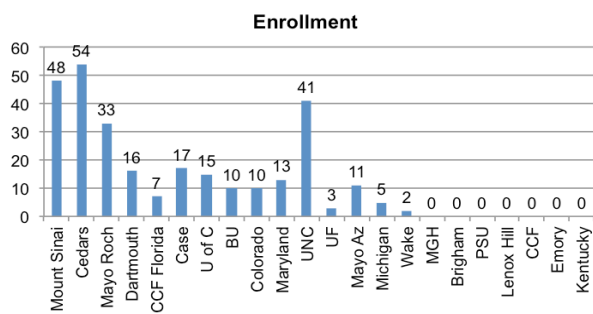
PUCCINI— Continued

Aim 3: To determine other risk factors associated with post-operative infection in IBD patients undergoing intra-abdominal surgery and explore analytic morphomic measurements as novel predictors of post-operative outcomes.

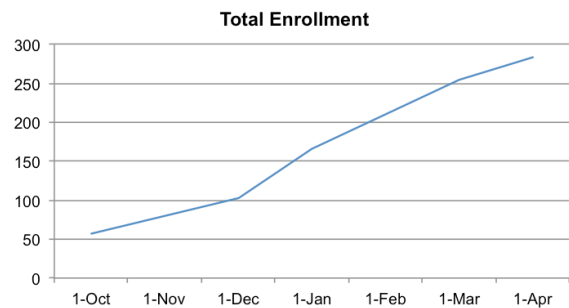
Status Update

- Funding for the CCFA Senior Research Award began in July 2013
- Enrollment began September 2014 and 283 patients have been enrolled up to April 2015. The goal is to enroll 1000 patients by early 2016.
- Sites are paid \$250 per patient enrolled.
- Centers currently enrolling include: Boston University Medical Center, Cedars-Sinai Hospital, Cleveland Clinic Foundation, Dartmouth-Hitchcock Medical Center, Lenox Hill Hospital, Mayo Clinic Arizona, Mayo Clinic Rochester, the Mount Sinai Hospital, Penn State Hershey, University of Chicago, University Hospitals Case Medical Center, University of Colorado, University of Florida, University of Maryland, University of Michigan Hospital, University of North Carolina Hospitals and Wake Forest University.
- Emory University and University of Kentucky have been accepted as additional sites. Contracts are still pending with Massachusetts General Hospital and Brigham and Women’s Hospital.

April 9, 2015 Enrollment (283)



Enrollment Progress as of 4/9/15 (283)



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APRIL: Autoimmune Paradoxical Reactions in IBD Longitudinal Cohort

PI: Millie Long



Background

The use of biologics, in particular anti-tumor necrosis factor-alpha (anti-TNF) agents, for the treatment of inflammatory bowel diseases (IBD) has increased dramatically in the United States over the past 2 decades. Overall, these agents have demonstrated safety and efficacy. However, reports of autoimmune reactions such as skin lesions (psoriasis), vasculitis, demyelinating disorders or drug-induced lupus are increasing. These reactions have been described as “paradoxical inflammation,” as they occur in patients on an anti-TNF therapy which was initiated with the intent to treat an inflammatory condition such as rheumatoid arthritis or IBD.

These reactions can be difficult to manage, and may result in discontinuation of an otherwise effective agent. Specific population-based risk factors for development of these paradoxical reactions are not known, nor are there formulation-specific data on risk. All of the currently available data have been collected retrospectively. As these series include relatively few patients and often do not have serum collected, data on serologic, genetic, or drug-level mediated risk are sparse. Preliminary data suggest a potential association with IL-23 receptor polymorphisms for psoriaform skin lesions, but further data are needed. Evidence-based treatment paradigms for paradoxical immune reactions are not known, with only small series of various medication trials in these reactions and limited data on cross-over reactions with re-initiation of alternate formulations of biologic agents.

Primary Aims:

1. To determine incidence and time to development of paradoxical immune reaction after initiation of a biologic agent
2. To determine risk factors for development of paradoxical immune reactions (factors may include drug levels, phenotypic, genetic or demographic data)

Secondary Aims:

1. To determine whether risks of paradoxical immune reactions differ by anti-TNF formulation and whether subsequent relapse occurs with alternate formulation.
2. To pilot the developed system as an electronic notification system of adverse reactions for FDA reporting.

Aims during pilot:

In the initial pilot phase of data collection, the aims will be to collect prospective baseline and follow-up (if applicable based on time of enrollment) clinical data on individuals on anti-TNF therapy. We will determine incidence, time to event, collect and store serum samples for future analysis, and obtain data confirming any paradoxical reaction and its treatment (medical records, consultations with dermatologists, and response to topical therapies). The goal enrollment during the pilot is 400 patients (80 per site), with a total of ~40 paradoxical reaction data collected.

STATUS UPDATE

Five sites are involved in the pilot study: University of North Carolina (primary), University of Maryland, University of Michigan, University of Florida, University of Washington- Harborview. Contracts are complete at all sites. The study is IRB approved at UNC and Michigan, with other sites in process. The database has been developed and is currently undergoing testing. The system has been developed for electronic follow-up of patients to minimize coordinator time. Sample collection protocol has been developed and approved by all sites. Monthly steering committee calls have been held per protocol. All milestones have been met, and we are on course for initial enrollment of patients at the primary site this summer, followed by secondary sites.

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EPIC Inflammatory Bowel Disease SmartForm

PI: James D. Lewis

Background

Currently, most documentation within commonly used Electronic Medical Records (EMR) is in the form of free text. The process of collecting this information is cumbersome and requires the physician to spend a substantial amount of time typing during the patient visit. If developed correctly, an IBD-specific EMR tool could increase physician satisfaction with their EMR. Likewise, if the physician is able to spend more time reviewing the treatment plan with the patient and less time typing, it is likely that patients' satisfaction will increase as well.

Clinical research in Inflammatory Bowel Disease (IBD) and gastroenterology in general has become increasingly complex and relies on electronic. Differences in documentation further complicate using clinical data to perform research. Available methods to electronically capture free text from EMRs for research are not easily adaptable to sharing data across research groups. A IBD specific tool that could capture clinical data using a defined vocabulary within discrete data fields would allow for more rapid sharing of data, thereby supporting collaborative research within the Clinical Research Alliance.

Epic is one of the leading EMR vendors within the United States, particularly within academic medical centers. Over the course of the last two years, Epic has partnered with University of Pennsylvania IBD program to develop the prototype of the IBD Smartform. It was developed to minimize the number of "mouse clicks" or key strokes needed to complete it. A key feature of the IBD Smartform is the ability to carry data forward between encounters, while allowing for all variables to be updated at any time. All data are time and date stamped for research purposes.

Specific Aims

1. Examine the process of implementing the IBD Smartform develop strategies for implementation
 - Develop a user's guide to facilitate implementation at other sites
 - Capture physicians' experiences using the tool
 - Modify, if necessary, the IBD Smartform based on initial users' experiences
 - Develop a data extraction algorithm and test it for accuracy
2. Determine whether the IBD Smartform facilitates collection of research quality data and has impact on physicians' satisfaction
 - Implement the tool at four clinical centers
 - Assess completeness and accuracy of data collection across multiple sites
 - Measure physicians' satisfaction with the tool

Status Update

The beta version of the IBD Smartform has been implemented at University of Pennsylvania and is being pilot tested by Drs. Lewis, Bewtra and Aberra. Weekly meetings with Epic are conducted to coordinate improvements to the beta version. Smartphrases are being developed and tested to facilitate automated note writing. In the next phase of the project, we will further refine the Smartform, develop training tools, and pilot test among other clinicians at Penn. We are also creating a list of sites who are potentially interested in participating in Phase 2 testing. If you are interested, please contact Lisa Nessel at nessel@mail.med.upenn.edu.

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RODIN-CD: A Randomized Controlled Trial of High-Dose Vitamin D in Crohn's Disease

PI: Shail Govani

Rationale

Patients with Crohn's disease (CD) are often vitamin D-deficient. Epidemiological and retrospective evidence exists to suggest that vitamin D levels play a role in the pathogenesis and disease activity of Crohn's disease (CD). While one small randomized controlled trial showed a trend towards reduction in relapse among patients given low doses of cholecalciferol, it remains unclear whether correction of vitamin D deficiency improves CD outcomes.

Hypothesis

We hypothesize that high dose vitamin D supplementation (10,000 IU for 60 days) among CD patients with vitamin D deficiency (serum 25-OH <20 ng/ml) does not cause hypercalcemia and improves clinical outcomes compared to supplementation with 400 IU daily for 60 days.

Aims

Aim 1: Compare clinical outcomes (CD-related surgery, CD-related hospitalizations, CD-related Emergency Department visits, and steroid prescriptions) between patients given high dose vitamin D3 versus low dose vitamin D3.

Aim 2: Compare adverse event rates (hypercalcemia and nephrolithiasis) between patients with patients given high dose vitamin D3 versus low dose vitamin D3.

Update

All of the sites (Michigan, Iowa, Indiana and UNC) have IRB approval and subcontracting is complete at all sites except UNC. Pharmacy dispensing operations have been set up at University of Pennsylvania. Iowa, Indiana and Michigan have started enrolling patients as of April 6th with a target of ~15 at each site.

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MERIT-UC (MEthotrexate Response In Treatment of UC)

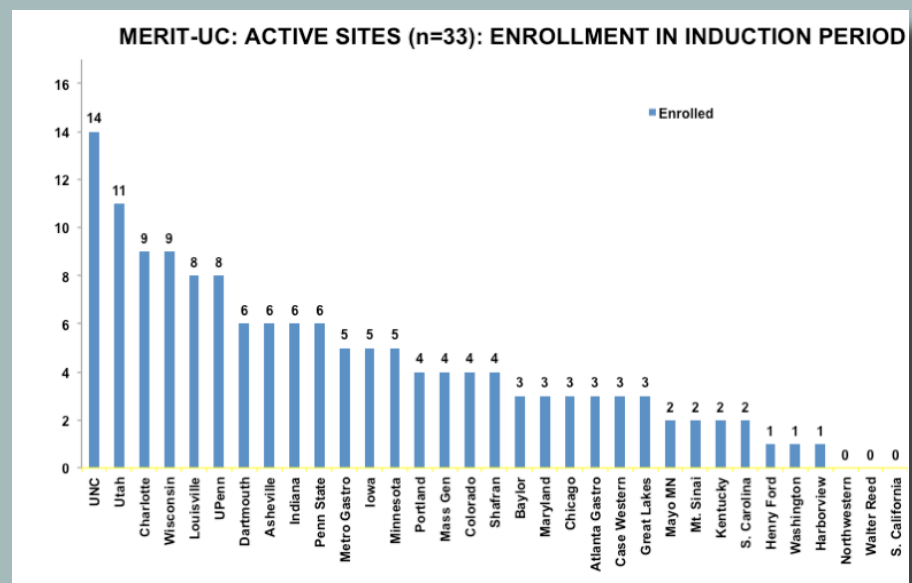
PI: Hans Herfarth

AIMS of MERIT-UC

MERIT-UC is a NIH funded multi-center prospective placebo controlled study to investigate the safety and efficacy of 25 mg MTX applied subcutaneously once weekly in patients with active UC, who are either steroid dependent or are intolerant or not responding to 5-ASA's or azathioprine/6-mercaptopurine therapy or have no response/ lost response to infliximab prior to the study inclusion.

The aims of the trial are:

1. To evaluate the safety and tolerability of 25 mg MTX applied sq once weekly over a time period of 48 weeks.
2. To evaluate the relapse-free survival of MTX maintenance therapy compared to placebo over a time period of 32 weeks.
3. To evaluate the efficacy of MTX over a time period of 16 weeks to induce steroid free remission.
4. To establish a DNA, plasma and serum library to enable the evaluation of clinical and pharmacogenomic models to predict the response to MTX therapy in patients with UC.



The study is 89% recruited and we aim to finish recruitment by end of June or July 2015. So far we have screened 213 patients for the study and included 150 into the study. 62 patients have been randomized at week 16. The current rate of response and/or clinical remission and no steroids since week 12 is 55%. Due to the results of the French METOR study, which will be presented at DDW 2015 it is even more important to complete recruitment for this study to evaluate the efficacy of MTX in maintaining steroid free remission.

We encourage all sites to continue to actively recruit in the trial, which is the so far largest clinical trial study of the CRA. **Many thanks to the active recruiters for this study. As of April 2015 we need approx. 18-20 more patients to be included in the Induction period.**

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MARQUEE study

Does Mucosal Healing Matter for Clinically Quiescent Ulcerative Colitis?

PI: Mark Osterman

BACKGROUND

There is increasing evidence that patients with ulcerative colitis (UC) have better long-term outcomes, including lower rates of disease flares and also lower rates of hospitalization and surgery, if their gut mucosa is healed. However, no study so far has examined whether treating with medication to the point of mucosal healing irrespective of clinical symptoms is an effective or warranted strategy. The purpose of the proposed study is to determine the proportion of UC patients in clinical remission with active mucosal disease on endoscopy and on histology during routine surveillance colonoscopy. We plan to determine whether the endoscopic activity correlates with biopsy findings. We will then use this information to calculate the risk of clinical disease flare in UC patients depending on their level of endoscopic and histological disease activity. The overall goal is to use all of the above information to plan a large randomized trial in which patients with clinically inactive UC will either remain on 5-ASA medications or step-up to immunosuppressives to determine whether treating with medication to the point of mucosal healing leads to improved clinical outcomes in the long run. We strongly suspect that achieving mucosal healing will lead to better health and quality of life in our UC patients.

AIMS

Primary Aims

1. To determine the prevalence of active endoscopic mucosal disease, defined by the Mayo endoscopic subscore, UCEIS, and UCCIS, in patients with clinically quiescent UC undergoing routine surveillance colonoscopy, both prior to and after stratification by baseline UC medication class (5-ASA, thiopurine, anti-TNF)
2. To determine the prevalence of active histological disease (both acute and chronic inflammation), defined by the Riley Index and basal plasmacytosis, in patients with clinically quiescent UC undergoing routine surveillance colonoscopy, both prior to and after stratification by baseline UC medication class (5-ASA, thiopurine, anti-TNF)
3. To correlate the endoscopic findings with histological findings of acute and chronic inflammation.

Secondary Aims

1. To preliminarily determine the risk of clinical relapse by Mayo endoscopic subscore, UCEIS, and UCCIS, in patients with clinically quiescent UC undergoing routine surveillance colonoscopy, both prior to and after stratification by baseline UC medication class.
2. To preliminarily determine the risk of clinical relapse by Riley Index and basal plasmacytosis in patients with clinically quiescent UC undergoing routine surveillance colonoscopy, both prior to and after stratification by baseline UC medication class.

STATUS UPDATE

Five sites are involved in the pilot study: University of Pennsylvania (primary), University of North Carolina, University of Michigan, University of Maryland, and Beth Israel Deaconess Medical Center. The study started enrolling April 2014, and as of 4/22/15, 89 of the planned 100 patients have been enrolled, with 48 patients having completed the 3-month follow-up visit, 34 having completed the 6-month follow-up visit, and 13 having completed the 9-month follow-up visit.

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PIANO: Pregnancy in Inflammatory Bowel Disease And Neonatal Outcomes

PI - Uma Mahadevan

Enrollment

1. 1417 Enrolled as of 3/2015
2. 565 enrolled in the long-term extension
3. Current enrollment is limited to mothers on anti-TNF agents (goal 150)
 - Ustekinumab 5 patients during pregnancy
 - Vedolizumab 2 patients during pregnancy
 - Golimumab 2 patients during pregnancy

Check anti-TNF Levels

1. Anti-TNF levels will be checked at birth in mother, cord and infant. If levels detectable, will check infant at 3 months; if detectable at 6 months.
2. If you have a patient enrolled who is on anti-TNF therapy they will be eligible for this. We would really LOVE to capture these patients.
3. 78 patients have delivered, 18 waiting to deliver

Optional

1. If a patient is on anti-TNF we would like to check breast milk samples in a small number of patients. Ideally the tubes will be mailed out with the kits for delivery. These kits will be mailed to the patient in the third trimester with a copy of her consent form and a letter to the OB with instructions
 - 52 breast milk results received
2. Response to vaccines will also be measured in all infants greater than 7 months of age. This is part of standard of care to see if they responded to their vaccines given immunosuppression use. We can enroll any existing PIANO patients in this regardless of medication exposure. We are targeting 300-400 patients.
 - 1 vaccine results received
3. T and B cell development. This is a substudy, separately funded, where we are measuring T and B cell development in children exposed to anti-TNF in utero. We are looking for specific populations.
 - 30 exposed and 30 unexposed 1-year old infants of IBD mothers studied
 - Exposed will be 25 INF/ADA plus AZA/6MP; 5 CZP + AZA/6MP
 - Unexposed will be 10 CZP without AZA/6MP; 10 AZA/6mp only; 10 no biologic/IMM
 - 5 T and B cell results received

One oral presentation and one poster session accepted at DDW

1. IMIBD Plenary- Detection of biologic agents in breast milk and implication for infection, growth and development in infants born to women with inflammatory bowel disease: Results from the PIANO Registry
2. Poster of Distinction- Insufficient weight gain during pregnancy in maternal IBD predicts adverse pregnancy outcomes: Results from the PIANO and Norwegian Registry

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