CLINICAL RESEARCH ALLIANCE
newsletter

CROHN'S & COLITIS FOUNDATION OF AMERICA

Clinical Research Alliance Meeting

Monday, May 23, 2016
11:30 AM - 2:00 PM
Hilton Bayfront
Sapphire 411

11:30 Lunch
12:15 Status of the CRA and call for applications 2016 (H. Herfarth, P. Higgins)

Update of CRA Studies

12:20 MERIT-UC (H. Herfarth)
12:25 PUCCINI (B. Cohen)
12:30 MARQUEE (M. Osterman)
12:35 EPIC Smartform (M. Bewtra)
12:40 PIANO (U. Mahadevan)
12:45 APRIL (M. Long)
12:50 SAPPHIRE (S. Itzkowitz)
12:55 Lessons from RODIN - CD (S. Govani, P. Higgins)
13:05 Plexus (J. Lewis)
13:10 Discussion
13:20 NEW PCORI / CRA Clinical Trial: The effectiveness of a specific carbohydrate diet versus a Mediterranean diet among patients with Crohn's disease. (J. Lewis)
13:30 TOPIC: Author rules, Phase 4 studies in CRA (H. Herfarth, P. Higgins)
13:45 Adjourn

SAPPHIRE: Safety of Immunosuppression in a Prospective Cohort of Inflammatory Bowel Disease Patients With a History of Cancer

PI – Steven Itzkowitz

Background

It is well established that certain IBD therapies are associated with developing cancer. For example, anti-TNF therapy may be associated with melanoma, and thiopurine therapy is associated with non-melanoma skin cancers and lymphoma. However, a Danish nationwide study of 56,146 IBD patients exposed to anti-TNFs found no increased risk of cancer over a 3.7-year follow-up period. Whether or not de novo cancers in IBD patients are related to immunosuppression, clinicians caring for patients with IBD are frequently challenged with questions about IBD management once a cancer is diagnosed or even with a past history of cancer. Despite limited supportive clinical data, guidelines recommend withholding immunosuppression for at least 5 years after a diagnosis of cancer. To some extent, this depends upon the type of cancer. In the pursuit of regulatory approval, randomized controlled trials of IBD therapies (eg. anti-TNFs) purposely excluded patients with active malignancy, or a history of cancer within the last 5 years, because of concern for provoking cancer progression or recurrence.

We recently performed a retrospective study where we reviewed the charts of 333 patients with IBD who had a history of cancer and were subsequently treated with anti-metabolites and/or anti-TNFs, or neither (controls) (1). This work was made possible by using data from several institutions in NYC (and Massachusetts General Hospital) under the rubric of the newly formed New York Crohn's and Colitis Organization (NYCCO) consortium. The results demonstrated that during the follow-up period, 90 patients (27%) developed incident cancer. However, there was no statistically significant difference in time to, or type of, incident cancer among the groups. This suggests that immune modulating IBD medications may in fact not be associated with an increased risk of incident cancer in IBD patients who have a history of cancer. While encouraging, these findings deserve to be validated in prospective studies to help avoid some of the usual biases of retrospective studies.

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SAPPHIRE - Continued

This project will develop a prospective Registry of patients with IBD who have a history of cancer, and follow them for the development of new or recurrent cancer. We have named this the SAPPHIRE Registry: Safety of Immunosuppression in A Prospective Cohort of Inflammatory Bowel Disease Patients With a HIstoRy of CancEr.

Aim

To prospectively determine the risk of new or recurrent cancer in IBD patients with a history of cancer who receive immunosuppression, compared to a control group not treated with immunosuppression.

Hypothesis

The incidence of new or recurrent cancer in IBD patients is not influenced by either the presence or type of immunosuppression.

Endpoints

Primary endpoint: To compare the rates of incident cancer between IBD patients with a history of cancer who receive immunosuppressants to those who are not exposed to these medications.

Secondary endpoints: To compare whether the type and duration of immunosuppression affects the development of incident cancer.

Status Update

- The SAPPHIRE Registry was approved in January 2016, and funding begins in May 2016.
- For the pilot period, NYCCO sites will be used. NYCCO was founded in 2013 by Drs. Steven Itzkowitz and Jean-Frederic Colombel from Mount Sinai, Drs. Seymour Katz and Mark Pochapin at NYU and Dr. Ellen Scherl at Weill Cornell Medical College It has evolved to include IBD investigators from most of the major academic medical centers in NYC (Mount Sinai, NYU, Columbia, Cornell, North Shore/Long Island Jewish Medical Center, Montefiore Medical Center, Lenox Hill Hospital, Winthrop Medical Center).
- Mount Sinai (coordinating site) just received IRB approval. Other sites are working on their IRB approvals.
- eCRFs are being built by the University of North Carolina Data Management Center.
- We expect to enroll 400 subjects in the first two years and follow them for 5 years for the development of new or recurrent cancer.
- Sites are paid $400 per patient ($200 at enrollment; $200 at patient completion).

Reference

1: Axelrad J, Bernheim O, Colombel JF, Malerba S, Ananthakrishnan A, Yajnik V, Hoffman G, Agrawal M, Lukin D, Desai A, McEachern E, Bosworth B, Scherl E, Reyes A, Zaidi H, Mudireddy P, DiCaprio D, Sultan K, Korelitz B, Wang E, Williams R, Chen L, Katz S, Itzkowitz SH; New York Crohn's and Colitis Organization (NYCCO). Risk of new or recurrent cancer in patients with inflammatory bowel disease and previous cancer exposed to immunosuppressive and anti-TNF agents. Clin Gastroenterol Hepatol. 14:58-64, 2016. PMID:26247164

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PUCCINI—Prospective Cohort of Ulcerative Colitisand 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 out comes

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

- 3-year funding for the CCFA Senior Research Award began in July 2013. A No Cost Extension was granted by the CCFA to continue the study through June 2017
- Enrollment began September 2014 and 775 patients have been enrolled through March 2016. Approximately one-third of patients have been anti-TNF exposed. The goal is to enroll 1000 patients by the end of 2016.
- Centers currently enrolling include: Boston University Medical Center, Cedars-Sinai Hospital, Cleveland Clinic Foundation, Dartmouth-Hitchcock Medical Center, Emory University, 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.

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EPIC IBD SmartForm

PI: James D. Lewis

The program to evaluate the functionality and accuracy of an electronic medical record SmartForm is underway. CCFA in cooperation with the University of Pennsylvania has partnered with 11 gastroenterology clinical practices from around the United States to implement an inflammatory bowel disease (IBD) SmartForm within Epic, a widely used health record software.

This SmartForm will aid physicians in the collection of targeted health information pertinent to patients with IBD. The use of predefined smart phrases will allow for more complete medical documentation relevant to IBD. In addition, this SmartForm is designed to allow uniform data collection across clinical practices creating harmonized data that can readily be used for research purposes.

All sites will provide physician satisfaction surveys to provide feedback about its ease of use, and efficiency. Some sites will also abstract medical record data to evaluate the accuracy of data collected within the SmartForm (these sites are mark with an asterisk). The sites are:

Cedars-Sinai Medical Center

The Carle Foundation

University of Florida

University of North Carolina

University of Utah

University of Wisconsin

University of California Los Angeles*

University of California San Diego*

University of California San Francisco*

University of Michigan*

University of Pittsburgh Medical Center*

Sites are in the process of loading the final SmartForm and will begin using it in late Spring 2016.

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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

By January of 2016, 18 patients had been screened and 11 were randomized. The pace of enrollment was slower than we anticipated. In January, we evaluated the reasons behind this by tracking patients who met our vitamin D criteria. We found that many patients either had active disease or were not interested in the study due to the requirements of the study. We evaluated methods to alter the study design to include patients with active disease but felt that such alterations would require a much larger sample size to detect differences. As a result of these discussions, we elected to close our study to enrollment in February of 2016.

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MERIT-UC (MEthotrexate Response In Treatment of UC)

PI: Hans Herfarth

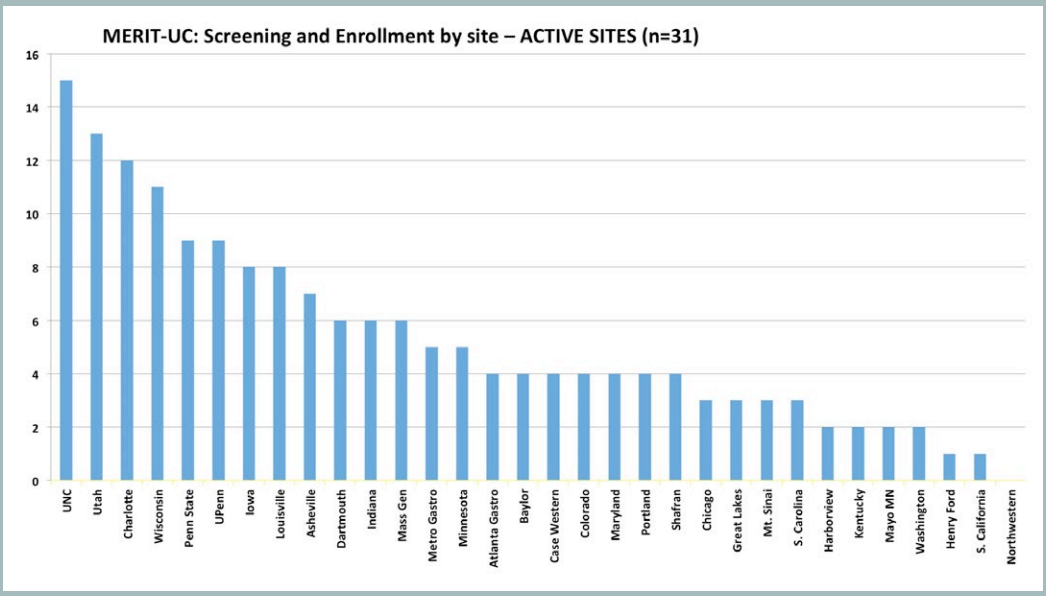
AIMS of MERIT-UC

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 99% recruited. So far, we have screened 254 patients for the study and included 177 into the study. 79 patients have been randomized at week 16. Based on the power analysis for the study, the aim is to randomize 80 or more patients, thus the study is nearly fully recruited.



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MARQUEE study

Does Mucosal Healing Matter for Clinically Quiescent Ulcerative Colitis?

PI: Mark Osterman

AIMS

This study investigates whether mucosal healing matters for clinically quiescent ulcerative colitis. This pilot study will potentially lay the groundwork for a future randomized controlled intervention trial in which patients in clinical remission but with evidence of endoscopic and/or histological disease activity despite optimized 5-ASA therapy would either remain on 5-ASA therapy or escalate therapy to thiopurines or anti-TNF agents to determine whether their future disease course could be modified.

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 centers of the Clinical Research Alliance are involved in this research: University of Pennsylvania (primary), University of North Carolina, University of Michigan, Beth Israel Deaconess Medical Center, and University of Maryland. The first patient was enrolled in April 2014 and the study completed enrollment by July 2015; a total of 100 patients were enrolled. The date of last patient follow-up will be July 2016. As of 3/17/15, all patients have completed the 3-month and 6-month follow-up visits; 81 patients have completed the 9-month and 12-month follow-up visits. With respect to centralized endoscopic and histological scoring, 70% of all endoscopic videos have been scored and 20% of all slides have been scored with the rest to follow shortly.

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PIANO: Pregnancy in Inflammatory Bowel Disease And Neonatal Outcomes

PI - Uma Mahadevan

Enrollment

1. 1518 Enrolled as of 5/2015
2. 630 enrolled in the long-term extension
3. Current enrollment is limited to mothers on anti-TNF agents (goal 150)
   - Ustekinumab 6 patients during pregnancy
   - Vedolizumab 11 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. We will re-check infant at 3 months; and again 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. 152 patients have delivered, 28 waiting to deliver (5 VEDO, 2 GOL)

Optional

1. The breast milk substudy is now complete.
   - 78 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 routine 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 100 patients.
   - 34 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; 10 INF/ADA without AZA/6MP
   - 19 T and B cell results received

Oral presentation at DDW 2016 May 22 @ 4:00PM

Do Infant Serum Levels of Biologic Agents at Birth Predict Risk of Infections?

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APRIL: Autoimmune Paradoxical Reactions in IBD Longitudinal Cohort

PI: Millie Long

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 Washington- Harborview, and University of Wisconsin. We had to select an alternate 5th site due to problems with contracting and IRB at an initially selected pilot site. The database has been developed, tested, and is currently being used for enrollment and follow-up without any issues. Email notifications to patients asking them to update status have been implemented to reduce coordinator burden and have this system function as a Phase IV registry for capturing adverse events. As of 4/2016, a total of 182 patients have been enrolled, with 16 paradoxical reactions identified (majority psoriaform reactions, with also a case of incident demyelination, and several cases of drug induced lupus reaction). A total of 99 patients have plasma and serum collected at baseline, cases additionally have serum and plasma collected at the time of event. We have applied for a no-cost extension to complete pilot enrollment in 2016 due to delays in initiating sites. Enrollment gone well once sites are up and running, and we have targets identified to complete enrollment by 12/2016. Next steps include assays on collected serum/plasma, application for a senior award for continued funding and for use in a proposed phase IV registry to capture AEs in patients on therapy with reduced burden on coordinators/sites.

Enrollment as of April 2016

University of North Carolina	110
Michigan	15
Maryland	42
Washington	15
Wisconsin	not enrolling yet

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