 **SCLERODERMA PROGRAM**  
  
General questions: [ssc\_coordinator@umich.edu](mailto:ssc_coordinator@umich.edu) For physicians: [khannad@med.umich.edu](mailto:khannad@med.umich.edu)

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| **STUDY** | **DESCRIPTION** | **CONTACT/PI** |
| **SKIN** | | |
| **ACT14604** | **Efficacy and safety of SAR156597 in the treatment of diffuse cutaneous Systemic Sclerosis (dcSSc): A randomized, double-blind, placebo-controlled, 24-week, proof of concept study**   * 24-week Double Blind/ 11 week follow up * 94 subjects * Some low dose background therapies are allowed (methotrexate < 15 mg, mycophenolate <2 g) * Weekly SAR156597/placebo 200 mg sub cutaneous injections. * Disease duration: <36 and mRSS >10 and < than 35 at screening * Currently approving visiting nurses for injections to limit travel time.8 onsite visits and 4 phone calls (on-site injections add additional injection only visits) * FVC < and DLCO corrected for hemoglobin <40% | **Recruiting Monica Sanborn** 734-232-2090 [monsan@med.umich.edu](mailto:monsan@med.umich.edu) **PI: Dr. Young** |
| **GSK2330811** | **A multi-centre, randomized, double-blind (sponsor open), placebo-controlled, repeat-dose, proof of mechanism study to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and explore efficacy of GSK2330811 in participants with diffuse cutaneous systemic sclerosis.**   * 12 week Double Blind/ 16 week follow up * 20-40 subjects across two cohorts * Some background therapies including mycophenolate (3 grams/stable dose last 3 months) and low dose oral corticosteroids (<10 mg stable 1 month) are allowed. * Bi- weekly 100/300 mg of GSK2330811 or placebo sub cutaneous injections. Totaling 6 injections of the course of the study. * Disease duration: <60 and mRSS >10 and < than 35 at screening plus additional active disease criteria: increasing skin involvement in the last 6 months, disease duration of <18 months or CRP of >6 mg/l) * FVC <50% of predicted or DLCO corrected <40% of predicted are exclusionary. * Optional blister biopsy | **Recruiting April 2018 Monica Sanborn** 734-232-2090 [monsan@med.umich.edu](mailto:monsan@med.umich.edu) **PI: Dr. Nagaraja** |
| **TOFA-SSc** | **Evaluation of tofacitinib in early diffuse cutaneous systemic sclerosis (dcSSc): A phase I/II two center safety and tolerability study**   * 24- week Double Blind/ 24 weeks of open label extension * 15 subjects across two centers * Some background therapies including mycophenolate (2 grams/1-month stable prior to baseline; methotrexate <25mg) and low dose oral corticosteroids (stable <10mg) are allowed. * Daily tofacitinib/placebo, 5mg, oral tablets BID * Disease duration: <60 and mRSS > 10 and <45 * Must have had Zostavax or be willing to obtain following protocol guidelines during screening. * FVC <50% of predicted or DLCO corrected <40% of predicted are exclusionary. * 4 visits + 1 phone during DB portion and 3 visits plus 2 phone calls for open label extension. * Biopsies at two time points | **Recruiting Monica Sanborn** 734-232-2090 [monsan@med.umich.edu](mailto:monsan@med.umich.edu)  **PI: Dr. Khanna** |
| **BRAVOS** | **Evaluation of Brentuximab Vedotin for Diffuse Cutaneous Systemic Sclerosis: A Phase ½ Multicenter Randomized, Double Blinded, Safety Study**   * Three ascending dose cohorts will receive brentuximab/placebo (0.6mg/kg, 1.2mg/kg and 1.8mg/kg. Each cohort will receive intravenous administration every 3 weeks for 21 weeks, with a total of 8 doses. 24 participants with 8 in each cohort. * Double blind treatment for 21 weeks followed by 27 weeks of follow up. * Disease duration: <60 and mRSS > 10 and <45 at screening plus additional active disease criteria: increasing skin involvement in the last 6 months or an mRSS that has not decreased >3 units within last 6 months or meets protocol specific criteria around SSc lung disease. * Documentation of at least 12 weeks of ongoing immunosuppressive therapy for SSc at time of enrollment with 4 weeks of stable dose for: methotrexate <25mg, mycophenolate <3g, or Azathioprine <3mg/kg/day. * FVC <60% of predicted or DLCO corrected <60% of predicted are exclusionary * Skin biopsies at two time points. | **Recruiting Monica Sanborn** 734-232-2090 [monsan@med.umich.edu](mailto:monsan@med.umich.edu)  **PI: Dr. Khanna** |
| **JBT-101** | **A Multi-Center, Randomized, Double-Blind, Placebo-Controlled Phase III Trial to Evaluate Efficacy and Safety of Lenabasum in Diffuse Cutaneous Systemic Sclerosis**   * Double blind treatment for 21 weeks followed by optional open label extension * 11 visits four to six weeks a part * 3 cohorts: 5mg, 20mg and placebo capsules with 1:1:1 randomization. * Disease duration: < 6 years from the first non-Raynaud’s. If duration is >3 years and less than 6, then mRSS must be > 15. * Overlap disease is allowed if SSc is the dominant clinical disease * Immunosuppressive therapy allowed, new or increased doses of medication should not occur within 8 weeks prior to screening. * Skin biopsies at two time points. | **Recruiting March 2018 Erica Bush** 734-936-5615 ebush@med.umich.edu  **PI: Dr. Nagaraja** |
| **DIGITAL ULCERS** | | | |
| **RESCUE** | **Pilot study to assess the efficacy and safety of riociguat vs. placebo in scleroderma –associated digital ulcers**   * 16 week double blind (8 week titration/8 week dose maintenance * 16 week Open Label * 20 subject, 5 centers * TID dosing of riociguat/placebo titrated up beginning with 1mg to 2.5 mg (0.5 is also available should tolerance be an issue) * Diagnosis of SSc and one visible, active, ischemic DU at baseline located at or distal to the proximal interphalangeal joint, and that developed or worsened within 8 weeks prior to screening. | **Recruiting Erica Bush** 734-936-5615 [ebush@med.umich.edu](mailto:ebush@med.umich.edu)  **PI: Dr. Nagaraja** | |
| **LUNG FIBROSIS** | | | |
| **SLS 3** | **Combining the anti‐fibrotic effects of pirfenidone (PFD) with mycophenolate (MMF) for treating scleroderma‐ related interstitial lung disease.**   * 18- month double blind, phase 2 with 1 month follow up visit * 150 subjects * Mycophenolate 250mg capsules + Pirfenidone 267mg capsules or placebo. The dosage will escalate if tolerated over a monthly 4 step titration plan. * FVC‐% of <80% at screening and Grade >2 on the Magnitude of Task component of the Mahler Modified Dyspnea Index are inclusionary. * FVS-% of 45% at screening or baseline; FEV1/FVC ration <0.68 at screening or baseline and DLCO corrected -% of 30% are all exclusionary. * Disease duration of <84 months * Extensive prohibited medication list with wash-out of at least 30 days, refer to protocol. | **Recruiting: Monica Sanborn** 734-232-2090 monsan@med.umich.edu  **Dr. Nagaraja** | |
| **JOINT CONTRACTURES** | | | |
| **REACH** | **Novel Rehabilitation Strategies to improve are function in patients with Scleroderma**   * Have a diagnosis of systemic sclerosis, diffuse cutaneous subset; disease duration < 5 years from 1st non Raynaud phenomenon sign or symptom * Have a contracture of the hand and other joint in at least one arm, such as wrist, elbow, or shoulder, with the ability to demonstrate active range of motion in that arm * Willing to travel to participate in therapy and outcome assessments. * Have an Android, iPhone, iPad or computer tablet to load the home exercise App | **Coming Soon Jennifer Serrano** 734-232-2090 monsan@med.umich.edu  **Dr. Khanna/Dr. Murphy** | |