ICTR COVID-19 Clinical Research Center Town Hall

Wednesday November 11, 2020
Town Hall Agenda

• Introduction of Deputy Directors
  Kelly Dooley, MD PhD
  David Hager, MD PhD

• Overview of current clinical research
  Mark Sulkowski, MD

• Navigating COVID-19 human subjects research at Johns Hopkins
  Stephanie Swords, MA, CCRP
  Lauren Sauer, MS
  Kim Kafka, BSN

• How to work with us
COVID-19 Clinical Research Center
Overview

• Mission: To facilitate COVID-19 clinical research at Johns Hopkins Medicine by supporting investigators and their study team members, establishing infrastructure for outpatient COVID-19 clinical studies, and providing a centralized location for access to University resources.

• Website: https://ictr.johnshopkins.edu/covid-research-center

• Leadership
  — Mark Sulkowski, MD, Director
  — Kelly Dooley, MD, MPH PhD and David Hager, MD, PhD, Deputy Directors for Outpatient and Inpatient Research
  — Lauren Sauer, PhD, Director of Operations, Office of Critical Event Preparedness and Response (CEPAR)
  — Kim Kafka, RN, BSN, Program Manager
  — Stephanie Swords, MA, CCRP, Research Operations
ICTR COVID-19 Clinical Research Center
Deputy Directors

• Dr. Dooley is an Associate Professor of Medicine & Pharmacology with appointments in Clinical Pharmacology and Infectious Diseases. She obtained her MD from Duke University and PhD from JHSPH. She is the JHU site leader for the outpatient COVID-19 research network, ACTIV-2. Her research focuses on tuberculosis therapeutics with an emphasis on clinical trials of TB drugs and HIV/TB co-treatment.

• Dr. Hager is an Associate Professor of Medicine. He obtained his MD from Cornell University and his PHD from the JHSPH. Dr. Hager is the Medical Director of the inpatient COVID-19 ICU and serves as Associate Director for the MICU. His research interests include sepsis, intermediate care, and mechanical ventilation strategies for acute lung injury.

• They will oversee outpatient and inpatient clinical research operations and will be responsible for establishing and implementing best practices for the ICTR COVID-19 Clinical Research Center
Overview of Current Therapeutic Clinical Research at Johns Hopkins
COVID-19 in Maryland, November 9, 2020

7-day moving average cases/100,000 persons

Hospital bed occupancy: ICU, Acute, Total
### NIH COVID-19 Treatment Guidelines Panel: Recommendation for Pharmacologic Management

<table>
<thead>
<tr>
<th>Disease Severity</th>
<th>Panel’s Recommendation</th>
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<tr>
<td>Prevention and prophylaxis of infection</td>
<td>• Do not use any agent except in a clinical trial</td>
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<tr>
<td>Non-hospitalized</td>
<td>• No specific therapy recommended except in a clinical trial [11/9 EUA for investigational monoclonal antibody therapy]</td>
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<td>Hospitalized and require supplemental oxygen</td>
<td>• Remdesivir (5 days, option for 10 days) (AI); or</td>
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<td>• Remdesivir plus dexamethasone (10 days) (BIII)</td>
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<tr>
<td>Hospitalized and require oxygen high-flow device or non-invasive ventilation</td>
<td>• Dexamethasone plus Remdesivir (AIII); or</td>
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<tr>
<td></td>
<td>• Dexamethasone (AI)</td>
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<tr>
<td>Hospitalized and require invasive mechanical ventilation or extracorporeal membrane oxygenation</td>
<td>• Dexamethasone (AI); or</td>
</tr>
<tr>
<td></td>
<td>• Dexamethasone plus Remdesivir (CIII)</td>
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Strength of recommendation: A, Strong; B, Moderate; C, Optional  
Quality of Evidence: I, One or more randomized trials with clinical outcomes and/or validated lab endpoints; II, One or more well-designed, nonrandomized trials or observational cohort studies; III, Expert opinion  
https://www.covid19treatmentguidelines.nih.gov/
Clinical trials for prevention of SARS-CoV-2 infection

• COVID-19 vaccines
  —Center for Immunization Research
  —Enroll: 410-955-7283 or Email JHSPH.ProjectSAVE@jhu.edu
  —COVID-19 Investigational Vaccine Study (CIR 339) Astra Zeneca
  —Pfizer (fully enrolled)
    ▪ PIs Anna Durbin MD and Kawsar Talaat MD

• Biomedical prevention for household contacts (and health care workers)
  —Convalescent plasma
    ▪ Enroll: 888-506-1199 or visit www.covidplasmatrial.org
    ▪ PI Shmuel Shoham, MD
  —Lambda interferon:
    ▪ Enroll: 410-314-1142 or Email PROTECT-study@jhmi.edu
    ▪ PI Mark Sulkowski
  —REGN-COV2 monoclonal antibodies (opening soon)
    ▪ PI Chloe Thio
Therapeutic trials for ambulatory patients with SARS-CoV-2 infection

• Convalescent plasma
  —Enroll: 888-506-1199 or visit www.covidplasmatrial.org
  —PI David Sullivan, MD

• ACTIV-2
  —Adaptive study design
  —Current drug: Bamlanivimab versus placebo (monoclonal antibody)
  —Enroll 410-955-2898 or visit www.riseabovecovid.org/
  —PI Kelly Dooley, MD PhD

• COMBO Trial (Camostat and bicalutamide) (opening soon)
  —PI Cathy Handy Marshal, MD
Therapeutic trials for hospitalized patients with mild to moderate COVID-19

• END-COVID: Molnupiravir (EIDD-2801), oral antiviral for 5 days
  — JHH, JHBMC, Howard County General Hospital, Suburban Hospital
  — PI Ashwin Balagopal

• CRITICAL: Crizanlizumab, monoclonal antibody targeting P-selectin
  — JHH, JHBMC, HCGH
  — PI Charlie Lowenstein, MD

• Adaptive COVID-19 Treatment Trial (soon ACTT-4)
  • ACTT-1 Remdesivir versus Placebo
  • ACTT-2 Remdesivir + Baricitinib versus Remdesivir + Placebo
  • ACTT-3 Interferon beta-1a + Remdesivir versus Remdesivir + Placebo
    — JHH
    — PI Noreen Hynes, MD MPH

• Prone positioning
  — JHH and JHBMC
  — PI Mahendra Damarla, MD
Therapeutic trials for hospitalized patients with severe COVID-19

• Novel arm restraint (COVID-19 and non-COVID-19 patients)
  — JHH, JHBMC
  — PI Dale Needham, MD PhD

• Clazakizumab, monoclonal antibody to IL-6
  — JHH, Howard County General Hospital
  — PI Nada Alachar MD

• Convalescent plasma
  — JHH, JHBMC
  — PI David Hager, MD PhD

• DART Trial: Decitabine (induce T regulatory cells)
  • JHH, JHBMC
  • PI Franco D’Alessio MD and Pali Shah, MD

• Cord Blood Derived T-Regulatory Cell Infusions
  — JHH
  — PI Doug Gladstone MD

• Acalabrutinib, Bruton's tyrosine kinase inhibitor
  — JHH
  — PI Brent Petty, MD

• OP-101 (dendrimer n-acetyl-cysteine)
  — JHH
  — PI Nauder Faraday MD MPH
Priority Guidance for Enrolling Hospitalized Patients in COVID-19 Clinical Trials

- Recruitment of hospitalized patients is guided by prioritization rank.
- After IRB approval and before recruitment, study PIs/teams present their study and implementation plans to the Clinical Research Coordinating Committee.
- Ranking by CRCC members is anonymous and updated with the initiation of new studies or the availability new information for ranked studies.
- Patient/LAR and attending preference for a specific study supersedes the priority ranking.
- Current priority guidance is online and shared on Microsoft Teams.

—Study Prioritization for Participants updated 11/2/2020 Current recruitment priority ranking of active protocols.
Impact of prioritization for patient recruitment

- Less imposition on patients and care teams
- More enrollment in therapeutic trials
- More coordination with non-interventional studies

Enrollment of hospitalized patients before and after prioritized recruitment

11.5% of 173 patients before prioritization
22.2% of 144 patients after prioritization

9/22/2020
Prioritization
Navigating COVID-19
Clinical Research at
Johns Hopkins
Planned clinical research

• Data resources only?
  — COVID-19 and Data Research Evaluation (CADRE) Committee
  — https://ictr.johnshopkins.edu/coronavirus/cadre/

• Biospecimens resources only?
  — COVID-19 Biospecimen Committee
  — https://ictr.johnshopkins.edu/coronavirus/biospecimencommittee/

• Involves direct interaction with participants and COVID-19?
  — COVID-19 Clinical Research Coordinating Committee
  — https://ictr.johnshopkins.edu/coronavirus/covid-johns-hopkins-clinical-research-coordinating-committee/
Clinical Research Coordinating Committee review is before submission to the COVID-19 IRB

While the CRCC has many goals, main priorities are:

• Enhance research participation across our health system
• Not overwhelm our patients with multiple requests regarding research participation
• Be sensitive to rapidly emerging data
• Limits to the number of treatment trials we can support
• Prioritize supplies such as PPE and reagent or specimen collection and transfer materials
• Minimize risks to patients, study participants, and staff

Apply to the CRCC

• When: Before submission to the IRB and ORA
• How: Application Form: https://ictr.johnshopkins.edu/coronavirus/clinical-research-coordinating-committee/
• Uncertain: COVID19ResearchCtr@jhmi.edu
Navigating COVID-19 Human Subjects Research

- Potential COVID-19 study
- CRCC Initial Review
- COVID-19 IRB Submission
- CRCC Prioritization Review
- Implementation
Guidance for the CRCC review

• Consult with the ICTR COVID-19 Clinical Research Center team
  — COVID19ResearchCtr@jhmi.edu

• Study team?

• Will the study recruit hospitalized patients?
  — Review current study priority guidance
    ▪ Study Prioritization for Participants
  — Request approval for hospital nursing leadership
    ▪ https://www.hopkinsmedicine.org/institutional_review_board/forms/jhhs_nursing.pdf
Guidance for the CRCC review

• Will the study team interact with participants with active SAR-CoV-2 infection?
  — Review HEIC guidance
    ▪ https://intranet.insidehopkinsmedicine.org/heic/novel_coronavirus/so_resources.html

• Will your study team collect/handle biologic specimens from patients with COVID-19?
  — Review the need for Biosafety Approval
    ▪ https://www.hopkinsmedicine.org/hse/forms/PathogenToxinRegistration.pdf
Guidance for the CRCC review

• Will the study recruit ambulatory patients with active COVID-19?
  — Medical isolation units (PODS) allow for visits with participants with active SARS-CoV-2 infection
  — Co-located with Johns Hopkins testing locations at Greenspring Station and Johns Hopkins Bayview Medical Center
  — Program manager: Kim Kafka, RN BSN
    — https://ictr.johnshopkins.edu/cru-online/
    — For more information: COVID19ResearchCtr@jhmi.edu
Guidance for the CRCC review

• Do you plan to recruit patients at Howard County General Hospital, Suburban Hospital or Sibley Memorial Hospital?

• Contact Johns Hopkins Capital Region Research (CAPRES)
  —https://ictr.johnshopkins.edu/capital-region-research-capres/
  —Program Director: Jackie Lobien, BSN, CCRP-CP
    ▪ jlobien1@jhmi.edu

• Outside of JHM? Johns Hopkins Clinical Trials Network
  —https://ictr.johnshopkins.edu/collaboration/collaborations/johns-hopkins-clinical-research-network-jhcrn/
  —Director: Adrian S. Dobs, MD, MHS
  —jhcrn@jhmi.edu
Guidance for after COVID-19 IRB approval

• Consult with the ICTR COVID-19 Clinical Research Center team
  — COVID19ResearchCtr@jhmi.edu

• Studies are reviewed by the Clinical Research Coordinating Committee for prioritization

• Recruitment resources
  — Microsoft Teams for JHH, JHBMC and HCGH
    ▪ Stephanie Swords, MA, CCRP
  — HOPE registry
    ▪ PI Dan Ford, MD MPH
    ▪ Program Manager: Cassie Lewis-Land
    ▪ Volunteers: http://johnshopkinshope.org/
    ▪ Researchers: https://ictr.johnshopkins.edu/programs_resources/programs_resources/research-participant-recruitment-and-retention-2/research-hop
COVID-19 Clinical Research Center
How to work with us

• Ask questions early and often
  — COVID19ResearchCtr@jhmi.edu

• Start at the ICTR COVID-19 CRC website
  — https://ictr.johnshopkins.edu/covid-research-center
  — Re-design underway to provide step-by-step guidance for human subjects and non-human subject research

• Join our monthly Town Hall Meetings
Questions

COVID-19 Clinical Research Center