



2021-2022

Approved Clinical Trials REPORT



الهيئة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY

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2022

APPROVED CLINICAL TRIALS

Sponsor	PI	Site	Study
SaNOtize Research & Development Corporation	Dr Jameela Al-Salman	AlShamil Field Hospital	Clinical efficacy study evaluating nitric oxide nasal spray (NONS) as prevention for individuals at risk of exposure to COVID-19 infection.
GlaxoSmithKline (GSK)	Dr Saadeya Naji	Salmaniya Medical Complex	LUNELORD: A descriptive, prospective study to assess demographic, pharmacologic, biomarker, clinical features and QoL of patients with Lupus Nephritis and long-term organ damage.
Novartis	Dr Jaffar Al Touq	Salmaniya Medical Complex	Amendment: A Phase II, multicenter, randomized, open label two arm study comparing the effect of crizanlizumab + standard of care to standard of care alone on renal function in sickle cell disease patients ≥ 16 years with chronic kidney disease due to sickle cell nephropathy (STEADFAST).

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Abu Dhabi Health Services Co (SEHA)	Dr Manaf Al-Qahtani	Bahrain International Hospital	Bi-directional (prospective or retrospective) real-world cohort study on sotrovimab and its impact on the strength and duration of the immune response to natural SARS-CoV-2 infection in real-life setting in the United Arab Emirates and the Kingdom of Bahrain.
Novartis	Dr Jaffar Al Touq	Salmaniya Medical Complex	Prospective, observational study in Sickle Cell Disease patients on crizanlizumab treatment in Middle East countries and India (SPOTLIGHT)
-	Dr Gowri Sivarama-krishnan	Halet Bu Maher Health Center	A Randomized Controlled Trial on the Remineralization Agents Used for the Treatment of White Spot Lesions.

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Novartis	Dr Jaffar Al Touq	Salmaniya Medical Complex	A Phase II, multicenter, randomized, open label two arm study comparing the effect of crizanlizumab + standard of care to standard of care alone on renal function in sickle cell disease patients ≥ 16 years with chronic kidney disease due to sickle cell nephropathy (STEADFAST).
Neopharma	Dr. Abdulla Darwish	BDF	An Open-Label, Pilot Study to Evaluate the Safety, Tolerability, and Efficacy of 5- Aminolevulinic acid phosphate and Sodium ferrous citrate (5-ALA-Phosphate +SFC) in Subjects with SARS-CoV-2 Infection (COVID-19)
Sinopharm	Dr. Manaf Alqahtani	Multi-site	Multicenter, Randomized, Double Blind, Parallel Placebo Controlled, Phase III Clinical Trial to Evaluate the Protective Efficacy, Safety and Immunogenicity of Inactivated SARS-CoV-2 Vaccines in Healthy Population Aged 18 years old and above

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RCSI Bahrain	Dr. Ghufran Jassim	BBK Hidd PHC	Randomised Controlled Superiority Trial of Fluticasone-Vilanterol as needed for the treatment of mild asthma in adults: a pilot randomized trial
Novartis	Dr Jaffar Al Touq	Salmaniya Medical Complex	Amendment: A Phase II, multicenter, randomized, open label two arm study comparing the effect of crizanlizumab + standard of care to standard of care alone on renal function in sickle cell disease patients ≥ 16 years with chronic kidney disease due to sickle cell nephropathy (STEADFAST).
SaNOtize Research and Development Corporation	Dr. Jameela AlSalman	AlShamil Field Hospital	A Double-Blinded, Placebo-Controlled Parallel, Phase 3 Clinical Efficacy Study Evaluating Nitric Oxide Nasal Spray (NONS) To Treat and Prevent the Exacerbation of Infection in Individuals with Documented Asymptomatic or Mild COVID-19

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Novartis	Dr Jaffar Al Touq	Salmaniya Medical Complex	Amendment: A Phase II, multicenter, randomized, open label two arm study comparing the effect of crizanlizumab + standard of care to standard of care alone on renal function in sickle cell disease patients ≥ 16 years with chronic kidney disease due to sickle cell nephropathy (STEADFAST).

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