Experiencia en estudios de investigacion

Pablo Andrés Moncada V.
Fundación Valle de Lili
Medicina Interna
Infectología

INTIC
Iniciativa Nacional para la Transformación de la Investigación Clínica

Fundación Valle del Lili

Cali

Centro de alta complejidad.

- Sur oeste
- Centro de referencia
- 606 camas
- May0 2021
- 200% ocupación.

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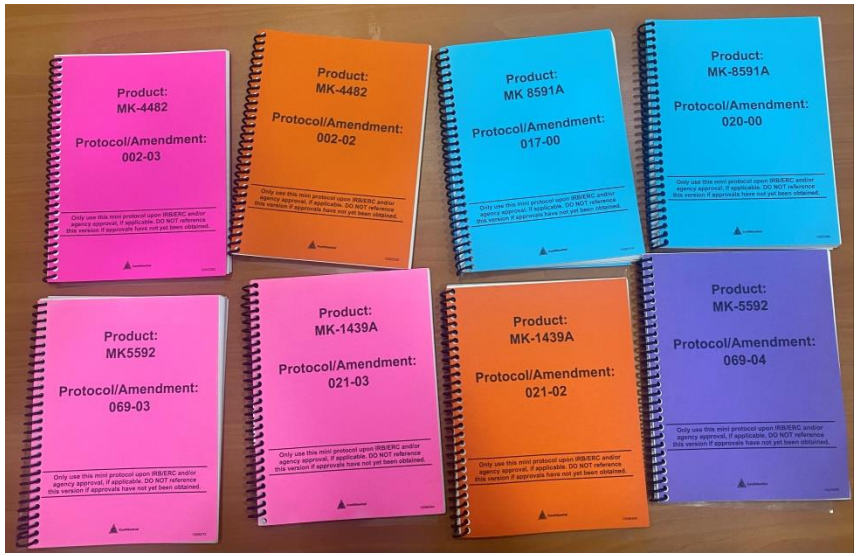

- Doravirine
- Posaconazol
- Islatravir
- Pneumococcal 15-valent conjugate Vaccine
- Molnupiravir
- V116

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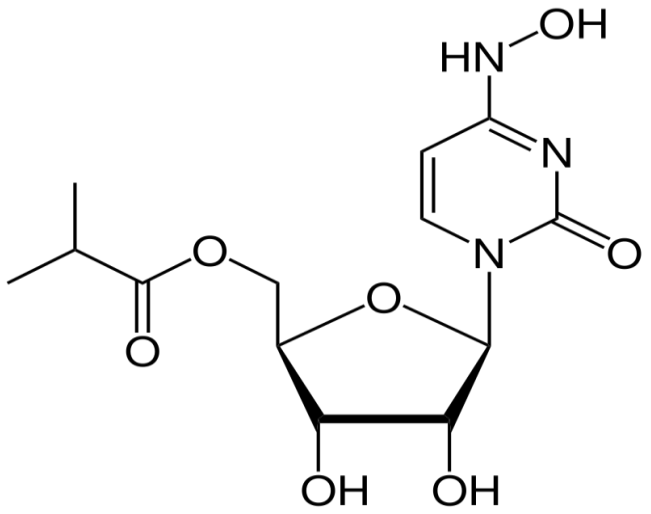
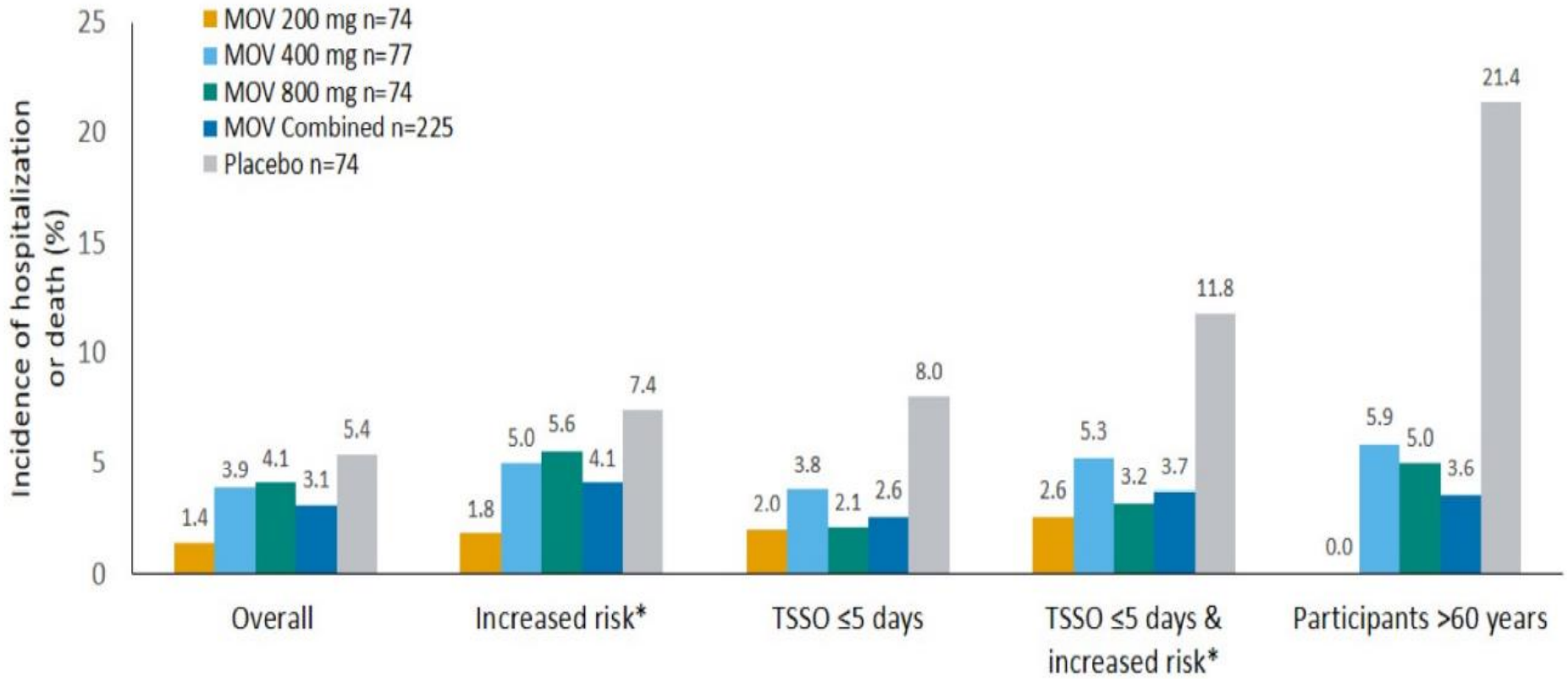


Figure reproduced from Sheahan TP, et al.

Primary Efficacy Endpoint (MITT Population)

MOV reduced the incidence of hospitalization or death through Day 29, particularly in subgroups with risk factors



CI, confidence interval. MOV, molnupiravir. MITT, modified intent to treat. n, number of participants included in the treatment arm. PBO, placebo. TSSO, time since onset of COVID-19 signs/symptoms to randomization. Corresponding confidence intervals are based on Miettinen & Nurminen method. The MITT population included all randomized participants who received ≥1 dose of study medication and was based on the study medication to which participants were randomized. *Protocol-defined risk factors were age >60 years, active cancer, chronic kidney disease, chronic obstructive pulmonary disease, immunocompromised/solid organ transplant recipient, obesity (body mass index ≥30), serious heart conditions (heart failure, coronary artery disease, and/or cardiomyopathies), diabetes mellitus, and sickle cell disease.

NEJM Evidence

Published December 16, 2021
NEJM Evid 2022; 1 (2)
DOI: 10.1056/EVIDoa2100043

ORIGINAL ARTICLE

Phase 2/3 Trial of Molnupiravir for Treatment of Covid-19 in Nonhospitalized Adults

Yoseph Caraco, M.D.[1], Gordon E. Crofoot, M.D.[2], Pablo Andres Moncada, M.D.[3], Anna Nikolaevna Galustyan, M.D.[4,5], Dany Badibanga Musungaie, M.D.[6], Brendan Payne, M.D.[7], Evgeniy Kovalchuk, M.D.[8], Antonio Gonzalez, M.D.[9], Michelle L. Brown, B.S.[10], Angela Williams-Diaz, B.S.[10], Wei Gao, Ph.D.[10], Julie M. Strizki, Ph.D.[10], Jay Grobler, Ph.D.[10], Jiejun Du, Ph.D.[10], Christopher A. Assaid, Ph.D.[10], Amanda Paschke, M.D.[10], Joan R. Butterton, M.D.[10], Matthew G. Johnson, M.D.[10], Carisa De Anda, Pharm.D.[10], on behalf of the MOVe-OUT Study Group

Abstract

BACKGROUND Safe and effective oral treatments are needed to improve clinical outcomes for nonhospitalized patients with Covid-19. Molnupiravir is an orally administered, small-molecule ribonucleoside prodrug shown to inhibit replication of severe acute respiratory syndrome coronavirus 2 in vitro and in animal models.

METHODS MOVe-OUT is an ongoing, phase 2/3, randomized, placebo-controlled, double-blind study evaluating the safety, efficacy, and pharmacokinetics of molnupiravir in nonhospitalized adults. In the phase 2 component, participants had mild or moderate, laboratory-confirmed Covid-19 with sign/symptom onset up to (and including) 7 days before randomization. Participants were randomly assigned 1:1:1:1 to receive 200, 400, or 800 mg of molnupiravir or placebo twice daily for 5 days, stratified by time since sign/symptom onset and by being at increased risk for severe illness from Covid-19. The primary efficacy end point was the proportion of participants who were hospitalized and/or died through day 29.

RESULTS The phase 2 component randomly assigned 302 participants to treatment; baseline characteristics were comparable across treatment groups. Molnupiravir had no apparent dose-related effect on adverse events, and no clinically meaningful abnormalities in laboratory test results were observed in relation to dose or treatment. Eleven participants were hospitalized or died through day 29. Of 225 participants in the combined molnupiravir group, 7 (3.1%) were hospitalized or died, compared with 4 of 74 participants (5.4%) in the placebo group. Subgroup analyses suggested lower incidences of hospitalization and/or death in the molnupiravir versus placebo groups in participants older than 60 years of age, those with increased risk for severe illness, those with symptom onset up to (and including) 5 days before randomization, and those with both symptom onset up to (and including) 5 days before randomization and increased risk for severe illness.

The author affiliations are listed at the end of the article.
Dr. Johnson can be contacted at matthew.johnson1@merck.com or at Merck & Co., Inc., 2000 Galloping Hill Rd., Kenilworth, NJ 07033.

Mayo 2021

valledellili.org.co

COVID-19

SECRETARÍA DEPARTAMENTAL DE SALUD

Actualización domingo, julio 11, 2021

CASOS COLOMBIA
4.511.960

VALLE DEL CAUCA
354.709
HOY 3.015

CALI
240.062
HOY 2.088

BUENAVENTURA
9.219
HOY 31

VALLE DEL CAUCA (SIN DISTRITOS)
105.428
HOY 896

MANEJO EN CASA
19.846

HOSPITAL
13.900
HOY 3.300

UCI
8.592
HOY 849

FALLECIDOS
10.954
HOY 77

RECUPERADOS
319.760

VALLE DEL CAUCA

Distribución de Casos por Municipio de Residencia

Nombre Municipio	Casos Positivos Día	Casos Positivos Acumulado	Proporción (%)	Casos Mortalidad Día	Casos Mortalidad Acumulados
Cali	2.088	240.062	67,68%	45	6.244
Buenaventura	31	9.219	2,60%	1	465
Palmira	156	20.328	5,73%	8	928
Tuluá	98	13.295	3,75%	3	566
Buga	94	9.906	2,79%	4	304
Cartago	69	9.686	2,73%	1	388
Jamundí	68	7.776	2,19%	2	201
Yumbo	101	6.632	1,87%	3	232
Candelaria	32	3.352	0,94%	1	142
El Cerrito	21	2.657	0,75%	4	129
Zarzal	25	2.281	0,64%	1	89
Florida	14	2.293	0,65%	0	169
Roldanillo	16	3.059	0,86%	1	100
Sevilla	24	2.916	0,82%	0	71
Pradera	0	1.553	0,44%	0	109
Dagua	13	1.427	0,40%	1	76
Guacarí	13	1.418	0,40%	1	58
Caicedonia	20	1.856	0,52%	0	74
Ginebra	8	823	0,23%	0	30
Bugalagrande	11	1.034	0,29%	0	41
La Unión	8	1.396	0,39%	0	77
Obando	6	576	0,16%	1	45
Andalucía	7	739	0,21%	0	47
San Pedro	18	728	0,21%	0	19
Calima	8	1.069	0,30%	0	31
Alcalá	9	495	0,14%	0	25
Vijes	10	548	0,15%	0	24
Restrepo	3	716	0,20%	0	31
Yotoco	2	620	0,17%	0	23
Trujillo	0	606	0,17%	0	23
Ansermanuevo	2	512	0,14%	0	44
Toro	7	400	0,11%	0	19
Riofrio	3	348	0,10%	0	29
La Cumbre	6	429	0,12%	0	18
La Victoria	5	552	0,16%	0	36
Versalles	2	354	0,10%	0	4
Ulloa	6	187	0,05%	0	6
El Dovio	0	257	0,07%	0	12
Bolivar	3	240	0,07%	0	10
Argelia	6	142	0,04%	0	7
El Cairo	2	151	0,04%	0	4
El Águila	0	129	0,04%	0	4
Fuera del Valle	0	1.942	0,55%	0	0
Valle del Cauca	3.015	354.709	100%	77	10.954

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COMUNICADO
Fundación Valle del Lili

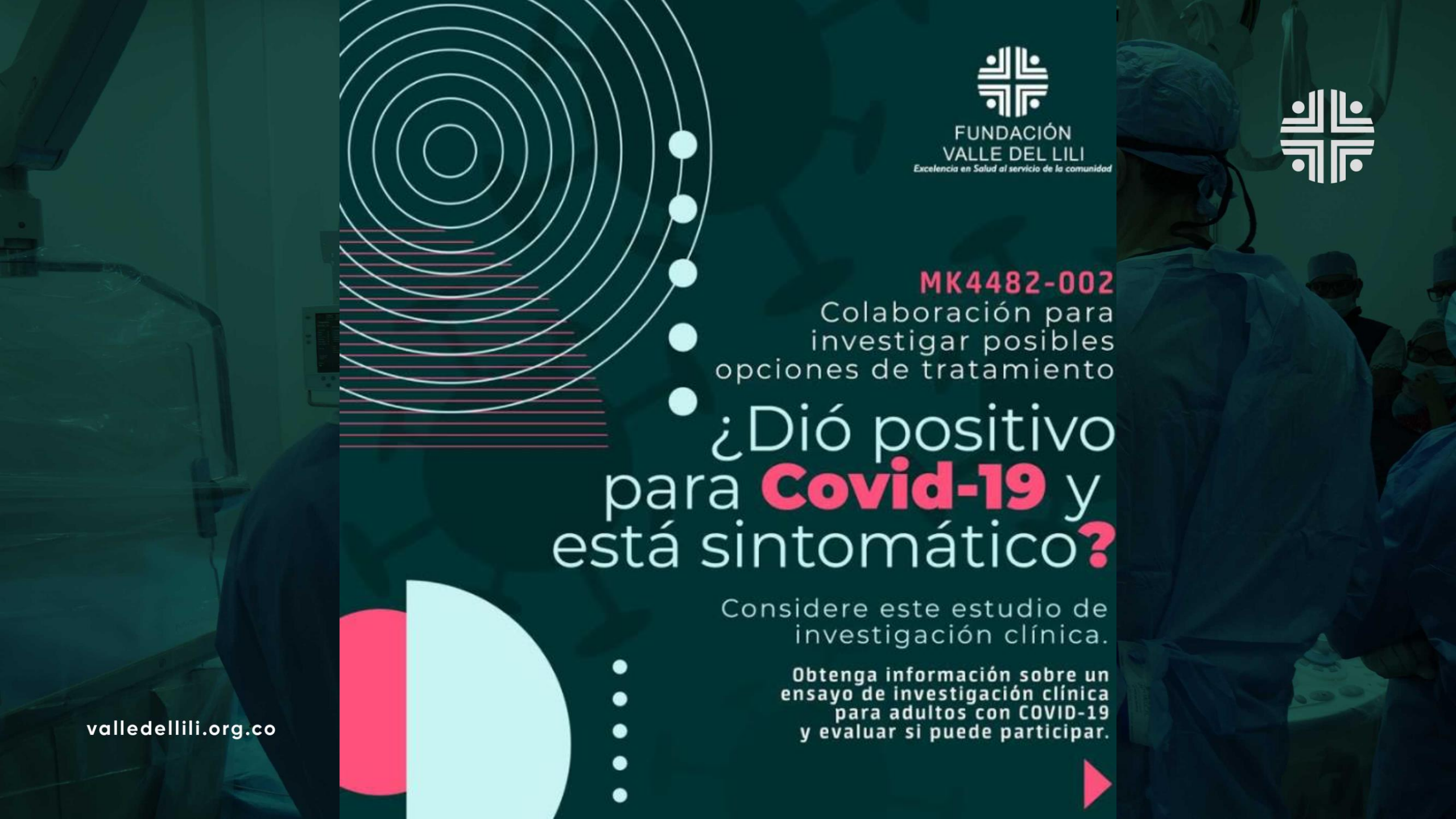
Santiago de Cali, junio 21 del 2021
Hora: 3:00 p.m.

La Fundación Valle del Lili informa que debido a la situación actual de la pandemia provocada por el SARS-COV-2, la Institución se declara nuevamente en estado de emergencia hospitalaria. **Nuestras áreas dedicadas a la atención de pacientes con enfermedad respiratoria presentan niveles de ocupación superior al 200% de nuestra capacidad.** Por esta razón y en conjunto con el Centro Regulador de Urgencias, Emergencias y Desastres (CRUE) para los pacientes con diagnóstico confirmado de Covid - 19, se definirá la Institución Prestadora de Salud (IPS) que, de acuerdo con el nivel de complejidad del caso, será la entidad que maneje el paciente y se realizará el debido proceso de remisión.

Ante esta situación, hacemos un llamado a la comprensión y solidaridad e invitamos a la comunidad a continuar con los protocolos de autocuidado, uso correcto del tapabocas, lavado de manos frecuente, distanciamiento físico y evitar aglomeraciones para disminuir el riesgo de contagio de COVID-19.

Nuestros servicios de Urgencias no respiratorias, Hospitalización, Consulta Externa, Laboratorio Clínico e Imágenes Diagnósticas continúan operando normalmente para ofrecer a nuestros pacientes una atención oportuna y bajo todos nuestros estándares de calidad y bioseguridad con la que hemos venido operando desde el inicio de la pandemia.

Oficina de Comunicaciones
Fundación Valle del Lili.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MK4482-002
Colaboración para
investigar posibles
opciones de tratamiento
¿Dió positivo
para Covid-19 y
está sintomático?
Considere este estudio de
investigación clínica.
Obtenga información sobre un
ensayo de investigación clínica
para adultos con COVID-19
y evaluar si puede participar.
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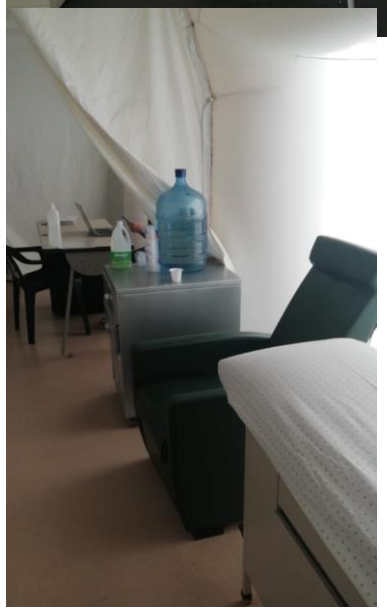
Durante este ensayo clínico, los investigadores pondrán a prueba un medicamento antiviral en estudio en personas que dieron positivo por **COVID-19** para saber:

- Cuál es la eficacia del medicamento contra COVID-19.
- En qué medida es seguro.
- En qué medida el organismo tolera el medicamento antiviral en estudio.
- Si el medicamento antiviral en estudio puede reducir los síntomas, el tiempo de recuperación y las hospitalizaciones.

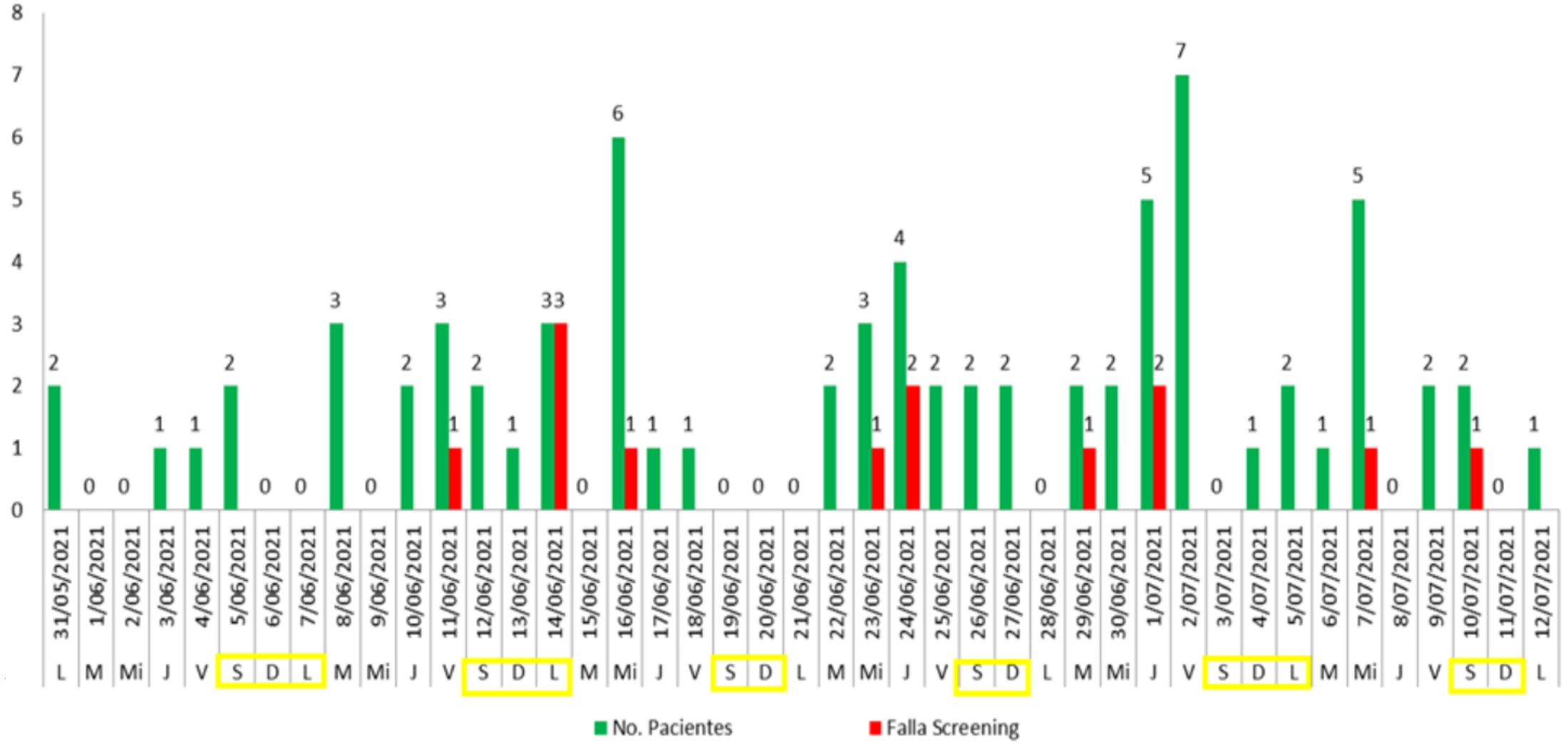


Escuchar este artículo

Estados Unidos acuerda compra de píldora anticovid si es aprobada por autoridades

Junio 09, 2021 - 11:52 a. m. | *Por: Agencia AFP*

Reclutamiento



Dificultades

- Información de familiares a posibles participantes
- Transporte inicial
- Estado del paciente para asistir a citas
- Paciente con alto valor pre-test
  - Ag SARS CoV 2 - Negativo
  - PCR - Sin aumento de la sensibilidad

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 FEBRUARY 10, 2022 VOL. 386 NO. 6

Molnupiravir for Oral Treatment of Covid-19 in Nonhospitalized Patients

A. Jayk Bernal, M.M. Gomes da Silva, D.B. Musungaie, E. Kovalchuk, A. Gonzalez, V. Delos Reyes, A. Martín-Quirós, Y. Caraco, A. Williams-Diaz, M.L. Brown, J. Du, A. Pedley, C. Assaid, J. Strizki, J.A. Grobler, H.H. Shamsuddin, R. Tipping, H. Wan, A. Paschke, J.R. Butterton, M.G. Johnson, and C. De Anda, for the MOVe-OUT Study Group*

ABSTRACT

BACKGROUND

New treatments are needed to reduce the risk of progression of coronavirus disease 2019 (Covid-19). Molnupiravir is an oral, small-molecule antiviral prodrug that is active against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

METHODS

We conducted a phase 3, double-blind, randomized, placebo-controlled trial to evaluate the efficacy and safety of treatment with molnupiravir started within 5 days after the onset of signs or symptoms in nonhospitalized, unvaccinated adults with mild-to-moderate, laboratory-confirmed Covid-19 and at least one risk factor for severe Covid-19 illness. Participants in the trial were randomly assigned to receive 800 mg of molnupiravir or placebo twice daily for 5 days. The primary efficacy end point was the incidence hospitalization or death at day 29; the incidence of adverse events was the primary safety end point. A planned interim analysis was performed when 50% of 1550 participants (target enrollment) had been followed through day 29.

RESULTS

A total of 1433 participants underwent randomization; 716 were assigned to receive molnupiravir and 717 to receive placebo. With the exception of an imbalance in sex, baseline characteristics were similar in the two groups. The superiority of molnupiravir was demonstrated at the interim analysis; the risk of hospitalization for any cause or death through day 29 was lower with molnupiravir (28 of 385 participants [7.3%]) than with placebo (53 of 377 [14.1%]) (difference, −6.8 percentage points; 95% confidence interval [CI], −11.3 to −2.4; P=0.001). In the analysis of all participants who had undergone randomization, the percentage of participants who were hospitalized or died through day 29 was lower in the molnupiravir group than in the placebo group (6.8% [48 of 709] vs. 9.7% [68 of 699]; difference, −3.0 percentage points; 95% CI, −5.9 to −0.1). Results of subgroup analyses were largely consistent with these overall results; in some subgroups, such as patients with evidence of previous SARS-CoV-2 infection, those with low baseline viral load, and those with diabetes, the point estimate for the difference favored placebo. One death was reported in the molnupiravir group and 9 were reported in the placebo group through day 29. Adverse events were reported in 216 of 710 participants (30.4%) in the molnupiravir group and 231 of 701 (33.0%) in the placebo group.

The authors' full names, academic degrees, and affiliations are listed in the Appendix. Dr. De Anda can be contacted at Merck, 309 Sumneytown Pike, North Wales, PA 19454.

*The members of the MOVe-OUT study group are listed in the Supplementary Appendix, available at NEJM.org.

This article was published on December 16, 2021, and updated on February 10, 2022, at NEJM.org.

N Engl J Med 2022;386:509-20.
DOI: 10.1056/NEJMoa2116044

Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Ref: Insp GCP 53095/25086832-0001
Inspection Site: Site 0401
Fundación Valle del Lili
Carrera 98 no 18-49
Cali, Valle del Cauca,
Colombia

Principal Investigator: Dr Pablo Moncada

Protocol: MK-4482-002
EudraCT: 2020-003368-24
Protocol Title: A Phase 2/3, Randomized, Placebo-Controlled, Double-Blind Clinical Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of MK-4482 in Non-Hospitalized Adults with COVID-19

Inspection Dates: 06 - 07 December 2021
Date documents requested: 22 November 2021
Pre-Inspection Requests to be provided electronically by: **01 December 2021**

Please note if any of the requests were provided for the main inspection and have not changed since that time please indicate this as we can access via the main inspection requests.

Annals of Internal Medicine ORIGINAL RESEARCH

Effect of Molnupiravir on Biomarkers, Respiratory Interventions, and Medical Services in COVID-19

A Randomized, Placebo-Controlled Trial

Matthew G. Johnson, MD; Amy Puenpatom, PhD; Pablo Andrés Moncada, MD; Lesley Burgess, MBChB, MMed, MSc, PhD; Elizabeth R. Duke, MD; Norio Ohmagari, MD, MSc, PhD; Timo Wolf, MD; Matteo Bassetti, MD, PhD; Sanjay Bhagani, BSc (Hons), MB, ChB; Jade Ghosn, MD, PhD; Ying Zhang, PhD; Hong Wan, PhD; Angela Williams-Diaz, BS; Michelle L. Brown, BS; Amanda Paschke, MD, MSCE; and Carisa De Anda, PharmD

Background: In the MOVe-OUT trial, molnupiravir showed a clinically meaningful reduction in the risk for hospitalization or death in adults with mild to moderate COVID-19 and risk factors for progression to severe disease.

Objective: To identify other potential clinical benefits of molnupiravir versus placebo.

Design: Secondary analysis of the randomized, double-blind, placebo-controlled phase 3 component of MOVe-OUT. (ClinicalTrials.gov: NCT04575597)

Setting: 107 sites globally.

Participants: 1433 nonhospitalized adults aged 18 years or older with mild to moderate COVID-19.

Intervention: Molnupiravir, 800 mg, or placebo every 12 hours for 5 days.

Measurements: Changes from baseline in C-reactive protein (CRP) concentration and oxygen saturation (Spo_2), need for respiratory interventions (including invasive mechanical ventilation), and need for medical services in all randomly assigned participants through day 29, and need for respiratory interventions and time to discharge in the subgroup of participants who were hospitalized after randomization.

Results: Participants receiving molnupiravir showed faster normalization of CRP and Spo_2, with improvements observed on day 3 of therapy, compared with placebo. Molnupiravir-treated participants had a decreased need for respiratory interventions versus placebo-treated participants (relative risk reduction [RRR], 34.3% [95% CI, 4.3% to 54.9%]), with similar findings in participants who were hospitalized after randomization (RRR, 21.3% [CI, 0.2% to 38.0%]). Hospitalized participants who received molnupiravir were discharged a median of 3 days before those who received placebo. Acute care visits (7.2% vs. 10.6%; RRR, 32.1% [CI, 4.4% to 51.7%]) and COVID-19–related acute care visits (6.6% vs. 10.0%; RRR, 33.8% [CI, 5.6% to 53.6%]) were less frequent in molnupiravir- versus placebo-treated participants.

Limitations: Some analyses were performed post hoc. Longer-term benefits of molnupiravir therapy were not evaluated. Participants were not immunized against SARS-CoV-2.

Conclusion: The findings suggest there are additional important clinical benefits of molnupiravir beyond reduction in hospitalization or death.

Primary Funding Source: Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc.

Ann Intern Med. doi:10.7326/M22-0729 **Annals.org**
For author, article, and disclosure information, see end of text.
This article was published at Annals.org on 7 June 2022.

SARS-CoV-2 is responsible for an unprecedented global pandemic that has resulted in 527 million cases and 6.3 million deaths worldwide as of 31 May 2022 (1, 2). The clinical presentation of SARS-CoV-2 infection varies; some people remain asymptomatic, whereas others develop COVID-19 that can range in severity from mild to critical illness resulting from a hyperinflammatory response to the virus (3, 4). Maintaining the availability of life-saving interventions, such as ventilatory and/or hemodynamic support, for all patients with severe or critical COVID-19 has been a major challenge throughout the pandemic, especially in regions with limited resources at baseline and during COVID-19 surges (5–8).

Immunization for COVID-19 decreases hospitalizations and progression to severe disease (9). However, many people remain unvaccinated due to lack of access or vaccine hesitancy (10, 11), breakthrough infections or death compared with placebo in nonhospitalized patients with COVID-19 who have risk factors for progression to severe disease (14–19). The effect of these therapies on other clinically relevant outcomes, such as changes in inflammatory markers, oxygen saturation (Spo_2), or ventilation requirements, in nonhospitalized patients or those requiring hospitalization after receiving these therapies has not been fully elucidated. The implementation of some of these therapies has been challenging (20), limiting their widespread availability and uptake globally. For instance, most mAbs and intravenous remdesivir must be administered in a medical setting (21–25), further burdening health care systems, limiting access for patients, and introducing infection control risks. Moreover, some mAbs are no longer recommended because they

MSD
INVENTING FOR LIFE

Otorga el presente reconocimiento a:

Fundación Clínica Valle de Lili

por su Excelencia en la Ejecución de Estudios Clínicos en Colombia

Noviembre 2022

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Reclutamiento de 106 para estudio V-116, vacuna conjugada pneumococo entre Febrero 20 a Marzo 8 2023

Estudio V-116, Abril 2023.

- Reclutamiento de pacientes mayores de 65 años con comorbilidades
  - Vacuna Neumococo conjugada 21 serotipos
  - Vacuna Neumococo polisacáridos 23 serotipos
  - Visita inicial y seguimiento a 30 días
- Tiempo reclutamiento menor de 3 semanas
  - Competitividad con otros centros mundiales
- Reclutamiento de 106 pacientes.
  - Calidad
  - Bienestar paciente.

Oportunidades y comentarios.

- Confianza centros
  - Experiencia
  - Autoría en literatura medica de primer nivel
  - Calidad
    - Médicos
    - Personal
    - Integridad
    - Comunicación
- Importancia
  - Ecosistema medico y financiero de las regiones.
    - Remuneración
    - Solvencia
    - Investigación original
- Concatenación.
  - Sector publico
  - Sector privado
- Bienestar del paciente.

Randomized Controlled Trial > JAMA. 2021 Dec 7;326(21):2161-2171.
doi: 10.1001/jama.2021.20714.

Effect of High-Flow Oxygen Therapy vs Conventional Oxygen Therapy on Invasive Mechanical Ventilation and Clinical Recovery in Patients With Severe COVID-19: A Randomized Clinical Trial

Gustavo A Ospina-Tascón [1 2], Luis Eduardo Calderón-Tapia [1 2], Alberto F García [1 2], Virginia Zarama [1], Freddy Gómez-Álvarez [1], Tatiana Álvarez-Saa [1], Stephania Pardo-Otálvaro [1], Diego F Bautista-Rincón [1], Mónica P Vargas [1], José L Aldana-Díaz [1 2], Ángela Marulanda [1 2], Alejandro Gutiérrez [1], Janer Varón [1], Mónica Gómez [1], María E Ochoa [1], Elena Escobar [1 2], Mauricio Umaña [1], Julio Díez [1], Gabriel J Tobón [3], Ludwig L Albornoz [3], Carlos Augusto Celemín Flórez [4], Guillermo Ortiz Ruiz [4], Eder Leonardo Cáceres [5], Luis Felipe Reyes [5 6], Lucas Petri Damiani [7], Alexandre B Cavalcanti [7]; HiFLo-Covid Investigators

Collaborators, Affiliations + expand

PMID: 34874419 PMCID: PMC8652598 DOI: 10.1001/jama.2021.20714

doi: 10.1001/jama.2019.0071.

Effect of a Resuscitation Strategy Targeting Peripheral Perfusion Status vs Serum Lactate Levels on 28-Day Mortality Among Patients With Septic Shock: The ANDROMEDA-SHOCK Randomized Clinical Trial

Glenn Hernández [1], Gustavo A Ospina-Tascón [2], Lucas Petri Damiani [3], Elisa Estenssoro [4], Arnaldo Dubin [5 6], Javier Hurtado [7 8], Gilberto Friedman [9], Ricardo Castro [1], Leyla Alegría [1], Jean-Louis Teboul [10 11], Maurizio Cecconi [12], Giorgio Ferri [13], Manuel Jibaja [14], Ronald Pairumani [13], Paula Fernández [15], Diego Barahona [16], Vladimir Granda-Luna [17], Alexandre Biasi Cavalcanti [3], Jan Bakker [1 18 19 20];
The ANDROMEDA SHOCK Investigators and the Latin America Intensive Care Network (LIVEN);

JAMA FULL TEXT

FREE Full text PMC

ACTIONS

Cite

Collections

SHARE

- Investigación original
  - Fortaleza institucional
  - Experiencia
  - Capacidades
  - Pacientes
  - Apoyo financiero

¡Gracias!