ISRCTN79981540 https://doi.org/10.1186/ISRCTN79981540

Safety of oral molnupiravir administration for hospitalized elderly COVID-19 patients aged 80 years old or older

Submission date
11/07/2022

Recruitment status
No longer recruiting

Registration date
15/07/2022

Overall study status
Completed

Last Edited
21/07/2022

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Oral molnupiravir has been found to be effective in the treatment of Covid-19 if it is initiated within 5 days after the onset of signs or symptoms in nonhospitalized, unvaccinated adults who were at risk of progression to serious disease, without obvious safety concerns. We evaluated the efficacy and safety of oral administration of molnupiravir to hospitalized elderly patients.

Who can participate?
Elderly people over 80 years of age with a risk factor for severe Covid-19

What does the study involve?
All participants receive molnupiravir within 24 hours of displaying symptoms of Covid-19

What are the possible benefits and risks of participating?
Oral administration of molnupiravir in the elderly aged 80 years and older is effective and is considered to potentially significantly improve outcomes.
If serious side effects are observed during oral administration, the administration should be stopped immediately. Safety monitoring was performed by the Data Monitoring Committee.

Where is the study run from?
Daido Central Hospital (Japan)

When is the study starting and how long is it expected to run for?
May 2022 to June 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Kenji Gonda, gondake@fmu.ac.jp

Contact information

Type(s)
Scientific

Contact name
Dr Kenji Gonda

ORCID ID
http://orcid.org/0000-0002-7671-1808

Contact details
1-1-37 Asato
Naha
Okinawa
Japan
902-0067
+81-98-869-0005
gondake@fmu.ac.jp

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Early treatment with molnupiravir in the elderly at risk for Covid-19

Study objectives
We evaluated the efficacy and safety of treatment with Molnupiravir.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/06/2022, Institutional Review Board of Daido Central Hospital, Daido Central Hospital, 1-1-37 Asato, Naha, Okinawa 902-0067, Japan; +81-98-869-0005; gondake@fmu.ac.jp), ref: No.35

Study design
Single centre longitudinal case-control study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not applicable (retrospective study)

Health condition(s) or problem(s) studied
Hospitalized elderly with at least one risk factor for Covid-19 disease

Interventions
We retrospectively evaluated the efficacy and safety of treatment with molnupiravir, which we started oral administration within 24 hours after the onset of signs or symptoms in hospitalized elderly with at least one risk factor for Covid-19 disease confirmed in the laboratory.
The follow-up observation period was 28 days during the treatment period and after the end of the treatment period, and the mortality rate was evaluated as efficacy and the adverse event incidence rate was evaluated as safety.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Molnupiravir

Primary outcome measure
Measured using patient records:
Adverse events are measured by seeing patients, 7, 14, 21 and 28 days.
1. Nausea, vomiting, anaphylaxis, and disturbance are measured within 7 days.
2. Massive sputum, anorexia and hypoxia are within 14 days.
3. Feeling dizzy, headaches and diarrhea are within 21 days.
4. Inedia and melena are within 28 days.

Secondary outcome measures
Measured based on the results of the clinical diagnosis by the attending physician:
1. Efficacy at 7 days
2. Safety within 28 days

Overall study start date
17/05/2022

Completion date
20/06/2022

Eligibility

Key inclusion criteria
1. Over 80 years of age
2. At least one risk factor of: age >60 years, active cancer, chronic kidney disease, chronic obstructive pulmonary disease, obesity defined by a body-mass index (the weight in kilograms divided by the square of the height in meters) ≥30, serious heart conditions (heart failure, coronary artery disease, or cardiomyopathies), diabetes mellitus, according to the guidance of Food and Drug Administration and World Health Organization (WHO)

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
29

Total final enrolment
29

Key exclusion criteria
1. The use of dialysis
2. Estimated glomerular filtration rate of 30 ml/minute/1.73 m^2 or less
3. Pregnancy
4. Neutropenia (neutrophil count of <500 / ml)
5. Platelet count <100,000/microliter
6. Monoclonal antibodies
7. Remdesivir

Date of first enrolment
17/01/2022

Date of final enrolment
17/07/2022

Locations

Countries of recruitment
Japan

Study participating centre
Daido Central Hospital
1-1-37 Asato
Naha
Okinawa
Japan
902-0067

Sponsor information

Organisation
Fukushima Medical University

Sponsor details
1 Hikarigaoka
Fukushima
Japan
960-1295
+81-90-4851-7823
suzukou8931@gmail.com

Sponsor type
University/education

Website
http://www.fmu.ac.jp/

ROR
https://ror.org/012eh0r35

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository.
Now, I have no repository name/weblink.
Type of data that will be shared is Fig and Table in my manuscript.
The data will become available after my manuscript is accepted and forever.
The data will be shared including with anyone else and all types of analyses.
The study was conducted according to the guidelines of the Declaration of Helsinki, and it was registered and approved by the Institutional Review Board of Daido Central Hospital (protocol code number: No.35, Jun 2022). Written informed consent was obtained from all patients and their families. Data were collected by the investigators and attending physicians, and interpreted by the authors. Data on adverse events were collected until the end of the follow-up observation period, and they were approved from all patients and their families for their storage, analysis, utilization, and publication of the data. The authors guarantee the accuracy and integrity of the data and the fidelity of the test protocol. In accordance with the Personal Protection Law, no patient name or family name will be published, and the subject patients will not be tracked or specified from this article.

IPD sharing plan summary
Stored in publicly available repository, Available on request