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Paxlovid in the treatment of COVID-19

Submission date	Recruitment status	[_] Prospectively registered
09/03/2023	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/03/2023	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/10/2023	Infections and Infestations	

Plain English summary of protocol

Background and study aims
Since the COVID-19 outbreak, the treatment of patients with COVID-19 pneumonia has been an issue of concern. At present, there is no specific drug for COVID-19, only symptomatic treatment, and the treatment of moderate and severe patients is a major difficulty. The emergence of nematavir/ritonavir tablets (PaxlovidTM) has brought new hope for the treatment of COVID-19 and has shown an effective inhibitory effect on the Omicron variant of COVID-19.

Who can participate?
Patients aged 12 years and over infected with the Omicron variant of COVID-19

What does the study involve?
Patients were retrospectively collected and divided into two groups according to the treatment regimen. Patients in both groups were given Lianhua Qingwen Capsule orally, three times/day, 6 g/time. The study group was given nirmatrelvir 300 mg/ritonavir 100 mg orally, every 12 hours, for 5 days, and the control group was not given any antiviral drugs. The two groups were compared in terms of the change in COVID-19 tests, hospitalization time and adverse drug reactions.

What are the possible benefits and risks of participating?
The study could play an important guiding role in the treatment of the COVID-19 Omicron variant in the future, and reduce the pain and disease burden of patients.

Where is the study run from?
Wenzhou Central Hospital (China)

When is the study starting and how long is it expected to run for?
January 2022 to December 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Chaochao Qiu, 790485628@qq.com

Contact information

Type(s)
Principal Investigator

Contact name
Mr Chaochao Qiu

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Paxlovid in the treatment of COVID-19

Acronym
PIT

Study objectives
The efficacy of nirmatrelvir/ritonavir in the treatment of the Omicron variant of COVID-19 was positive and had good tolerance in patients

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/11/2022, Ethics Committee of Wenzhou Central Hospital (252 Baili Dong Lu, Lucheng District, Wenzhou City, Zhejiang Province, China; +86 (0)577 88070000; weybgs@163.com), ref: L2022-04-082

Study design
Retrospective study

Primary study design
Interventional

Secondary study design
Retrospective study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not applicable

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection)

Interventions
58 cases infected with the Omicron variant of COVID-19 were retrospectively collected and divided into two groups according to the treatment regimen. Patients in both groups were given Lianhua Qingwen Capsule orally, three times/day, 6 g/time. The study group was given nirmatrelvir 300 mg/ritonavir 100 mg orally, q12h, for 5 days, and the control group was not given any antiviral drugs. The two groups were compared in terms of the change in CT values of COVID-19 nucleic acid, the negative conversion time of COVID-19 RNA, hospitalization time, adverse drug reactions, and COVID-19 nucleic acid re-positive.

Intervention Type
Drug

Phase
Phase III/IV

Drug/device/biological/vaccine name(s)
Nirmatrelvir/ritonavir

Primary outcome measure
CT values (CT values of 40 for negative results) of nasal swab COVID-19 nucleic acid tests on days 4, 7, 9 and 11 of treatment

Secondary outcome measures
1. First negative conversion time (or CT value ≥40) of COVID-19 nucleic acid tests
2. Hospitalization time, strictly according to discharge criteria
3. Adverse drug reactions recorded during hospitalization
4. COVID-19 nucleic acid re-positive in daily COVID-19 nucleic acid tests in the 7 days of isolation after discharge

Overall study start date
01/01/2022

Completion date
31/12/2022

Eligibility

Key inclusion criteria
1. Confirmation of COVID-19 infection within 24 h and positive nasopharyngeal swab for COVID-19 nucleic acid RNA
2. Age ≥12 years and weight ≥40 kg
3. Subjects of fertility must agree to use highly effective contraceptive methods

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
58

Total final enrolment
58

Key exclusion criteria
1. Previous history of COVID-19 treatment
2. A known history of active liver disease
3. Patients on renal dialysis or have moderate to severe impaired renal function
4. The known human immunodeficiency virus (HIV) infection
5. Suspected or confirmed concurrent active systemic infections other than COVID-19 infection
6. Allergy or other contraindication to any component of the study intervention
7. Any drug or substance that is currently or expected to be used that is a high reliance on CYP3A4 enzyme clearance or strong CYP3A4 enzyme inducers
8. Pregnant or breastfeeding women

Date of first enrolment
15/11/2022

Date of final enrolment
30/12/2022

Locations

Countries of recruitment
China

Study participating centre
Wenzhou Central Hospital
No. 252, Baili East Road
Lucheng District
Wenzhou City
China
325000

Sponsor information

Organisation
Wenzhou Central Hospital

Sponsor details
No. 252, Baili East Road
Lucheng District
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325000
+86 (0)86718290
790485628@qq.com

Sponsor type
Hospital/treatment centre

Website
https://www.wzhosp.com/

ROR
https://ror.org/00w5h0n54

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
20/04/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		13/07/2023	10/10/2023	Yes	No