**Title of Dataset:**

**Ivermectin in combination with doxycycline for treating COVID-19 symptoms: a randomized trial**

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3. Date of data collection: 2020/06/01 to 2020/08/30

4. Geographic location of data collection: COVID-19 unit, Dhaka Medical College, Dhaka, Bangladesh

5. Information about funding sources that supported the collection of the data: **Non-funded study**

SHARING/ACCESS INFORMATION

1. Licenses/restrictions placed on the data:

This work is licensed under a [CC0 1.0 Universal (CC0 1.0) Public Domain Dedication](https://creativecommons.org/publicdomain/zero/1.0/) license

2. Links to publications that cite or use the data: Dryad:

Dryad. doi:10.5061/dryad.qjq2bvqf6

3. Links to other publicly accessible locations of the data: None

4. Links/relationships to ancillary data sets: None

5. Was data derived from another source? No

A. If yes, list source(s):

6. Recommended citation for this dataset:

Reaz, Mahmud et al. (2021), **Ivermectin in combination with doxycycline for treating COVID-19 symptoms: a randomized trial**, Dryad, Dataset, Dryad. doi:10.5061/dryad.qjq2bvqf6

DATA & FILE OVERVIEW

1. File List:

Data set in SPSS

2. Relationship between files, if important:

3. Additional related data collected that was not included in the current data package:

4. Are there multiple versions of the dataset? No

A. If yes, name of file(s) that was updated:

i. Why was the file updated?

ii. When was the file updated?

METHODOLOGICAL INFORMATION

1. Description of methods used for collection/generation of data:

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2. Methods for processing the data:

Patients were enrolled between 1 June and 30 august, 2020. The inclusion criteria for enrollment were patients more than 18 years old, tested positive for COVID-19 within 3 days of a polymerase chain reaction test, and have mild to moderately severe disease. Patients who were unable to take oral medications, pregnant or breast feeding, had severe COVID symptoms [as defined by tachypnea (> 30 breaths/min), and hypoxia (SpO2 < 90%) on room air and requiring supplemental oxygen], were admitted to the intensive care or high-dependency units and had known hypersensitivities to either of the drugs were excluded from the trial. Demographic and other informations were obtained directly from the patients by the co-investigators.

Eligible patients were randomly assigned to one of the two treatment groups in a 1:1 ratio on day 1 of the trial by using simple randomization. Group assignment was not stratified by disease severity.

The allocation schedule was created with a list of random numbers generated with the random number generator program by the head of the department of Medicine of the institute who concealed group assignment in sequentially numbered, opaque, sealed envelopes. The randomization code was kept at the pharmaceutical company. Neither the investigators nor the patients were aware of group assignment.

**Procedure**

Base-line demographic and clinical characteristics were collected by data collectors on a case-record form. The date of random assignment was considered to be Day 1, and all patients received their initial treatment dose on Day 1. Outpatients were followed daily until they showed at least 3 days of clinical recovery. The Clinical recovery was defined as a normal body temperature 36.1°C to 37.2°C maintained for at least 3 days, significantly improved respiratory symptoms (respiratory rate <25/min, no dyspnea), and an oxygen saturation greater than 93% without assisted oxygen inhalation, as recommended by the World Health Organization and the national guideline of Bangladesh.

Hospitalized patients were followed from day 1 through day 14, or until discharge or clinical improvement, which ever was later. Clinical status and vital signs (including respiratory status) were recorded daily. Any adverse events as defined by the Medical Dictionary for Regulatory Activities (MedDRA) were documented.

Laboratory tests were done on day 1 and included complete blood count; concentrations of random blood glucose, creatinine, alanine transaminase, C-reactive protein, and ferritin; D-dimer, and either a chest radiograph or a chest CT scan, which one was feasible or needed. For outpatients, test results were documented in next visit. Hospitalized patients were tested on days 1 and 7 and when ordered by the treating physician. Real-time-polymerase chain reaction testing for COVID-19 was done 14 days after the initial positive test on all patients.

**Outcome Measures**

The primary outcome was the number of days required for clinical recovery as defined earlier, from day- 1. Clinical recovery was divided into three categories; early- recovered within 7 days, intermediate-recovered within 7 to 11 days and late-improvement required 12 or more days for recovery. Secondary outcomes were disease progression through mild, moderate, severe or death, and the proportion of patients who continued to test positive for SARS-CoV-2 on day14. Adverse drug reactions (adverse events assumed to be caused by the drugs) were also recorded. Mild disease was defined as the symptoms of an upper respiratory tract viral infection, including mild fever, dry cough, sore throat, nasal congestion, malaise, headache, muscle pain, anosmia or malaise. Moderate disease as respiratory symptoms such as cough and shortness of breath were present without signs of severe pneumonia. Severe disease as severe dyspnea, tachypnea (> 30 breaths/min), and hypoxia (SpO2 < 90% on room air). This classifications were made according to the World Health Organization and the national guideline of Bangladesh. The Co-investigators assessed the outcome, graded the disease and document the adverse reactions

3. Instrument- or software-specific information needed to interpret the data:

Data were analyzed using SPSS software, version 20 (Armonk, NY: IBM Corp, USA).

4. Standards and calibration information, if appropriate:

5. Environmental/experimental conditions:

6. Describe any quality-assurance procedures performed on the data:

7. People involved with sample collection, processing, analysis and/or submission:

**Principal investigator and Co-investigators of the study**

DATA-SPECIFIC INFORMATION FOR: [FILENAME]

1. Number of variables: 43

2. Number of cases/rows: 400

3. Variable List:

NOD: Nature of drugs 0=placebo, 1= active drug

Hospitalization: 0= not hospitalized, 1= Hosptalized

Age group of the patients: 1=<40 years, 2=40-60 years, 3=>60 years

Gender: male -1or female-0

Fever: presence-1 or absence-0

Cough: presence-1 or absence-0

Running nose: presence-1 or absence-0

Respiratory distress: presence-1 or absence-0

Sore throat: presence-1 or absence-0

Hoarseness of voice: presence-1 or absence-0

Chest pain: presence-1 or absence-0

Diarrhea: presence-1 or absence-0

Vomiting: presence-1 or absence-0

Anorexia: presence-1 or absence-0

Anosmia: presence-1 or absence-0

Headache: presence-1 or absence-0

Lethargy: presence-1 or absence-0

Conjunctivitis: presence-1 or absence-0

Body ache: presence-1 or absence-0

Total duration of illness: duration required to have clinical recovery

Interval: Interval between the onset of disease and intervention (application of drugs)

Symptom recovery: Interval between intervention and the time to recover.

Censored: 0=censored, 1= continue follow up

Status: 0=lost to follow up, 1= continue follow up, 2 adverse effect, 3= death

Conversion to next level of severity: presence-1 or absence-0

Persistent positivity: presence-1 or absence-0

Post Covid syndrome: presence-1 or absence-0

Co-morbidity: presence-1 or absence-0

Diabetes: presence-1 or absence-0

Hypertension presence-1 or absence-0

Others:

Severity of illness at presentation: Mild=1, moderate=2, severe=3

Drugs given within 7 days: Yes -1 No-0

Response within 7 days: Yes -1 No-0

Response within 7-11 days: Yes -1 No-0

Response after 12 days; Yes-1 No -0

Severity conversion: yes=1, No=0

Ultimate severity: severity At the end of follow up: Mild=1 moderate=2 and severe=3

Adverse effect: Response within 7 days: Yes -1 No-0

Comorbidity single: mere presence or absence of any co-morbidity, 0= absent, 1=present

Final status: 0=censored, 1 = continue follow up

Outcome death or alive: 0= death, 1=alive

4. Missing data codes: 99, 98 etc

5. Specialized formats or other abbreviations used:

**Clinical Recovery:**

**Clinical improvement or recovery** in patients was assessed according to the improvement criteria of the WHO and Bangladesh guidelines which required that the body temperature remained normal for at least 3 days, respiratory symptoms were significantly improved (respiratory rate < 25 and no dyspnea), and SpO2 >93% was achieved without assisted oxygen inhalation.

Respiratory distress; Shortness of breath, respiratory rate >25/min, or oxygen saturation <93%

Severity of the disease:

**Mild disease** was defined as the symptoms of an upper respiratory tract viral infection, including mild fever, cough (dry), sore throat, nasal congestion, malaise, headache, muscle pain, anosmia, or malaise.

**Moderate disease**, including respiratory symptoms, such as cough and shortness of breath are present without signs of severe pneumonia.

**Severe disease** included severe dyspnea, tachypnea (> 30 breaths/min), and hypoxia (SpO2 < 90% in room air). These classifications were made according to the World Health Organization and national guidelines of Bangladesh.

In this study, we assessed the proportion of patients with **early recovery** (clinical improvement within 7 days of symptom onset), **late recovery** (clinical improvement required ≥12 days),

**Severity conversion** (patients progress to more serious disease),

**Persistently positive** for RT-PCR of COVID-19 (positive RT-PCR on a 14 day test), and

**Post-COVID syndrome** (in the absence of any definition, we defined it as 1. Persistence of illness with signs and symptoms beyond virologic clearance 2. Development of new symptoms within 1 month after the initial clinical and virologic cure, the etiology of which is postulated to be viral infection.