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Original Research Article

Study of clinical trials for the management of COVID-19 outbreak registered in the Clinical Trial Registry-India

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ABSTRACT

Context: After China, now COVID-19 is spreading all over the world in about 212 countries and territories. In India, over 46008 active, 22454 recovered, 2293 death, and 1 migrated case (a total of 70756 cases) has been reported till 12th May 2020.
Aims: This study has been designed to review the currently registered clinical studies in Clinical Trials Registry-India. The study provides the overall summary and insight into diagnostic tools, treatment, and preventive strategies for COVID-19.
Settings and Design: All the clinical trials (including clinical studies) registered in Clinical Trials Registry-India between 31 March 2020 to 11th May 2020 were reviewed and analyzed.
Materials and Methods: The registered studies in CTRI (ctri.nic.in) were searched in the "Trial Search" option with keywords such as "COVID-19", "Corona Virus", "SARS-CoV2", and "2019 nCoV".
Statistical analysis used: NA.
Results: A total of 57 trials over COVID-19 have been registered in CTRI within the last three months (i.e. 1st March 2020 to 11th May 2020).
These trials include 40 interventional trials and 17 clinical studies. The interventional studies include the drug, biologics, ayurvedic, homeopathic, diagnostic, nutritional, and process of care change.
Conclusions: The world is combating against the COVID-19 outbreak. The availability of new health intervention against COVID-19 needs the more scientific, and collaborative center of attention towards drug development and clinical trials for COVID-19.
Key Messages: The fast track approval of clinical trials, effective study design, making informed consent more "inform", planning and scientific consideration over sample size, development of data safety monitoring board to supervise and ensure trial participant's safety may enforce the successfulness of trial completion.

1. Introduction

On 31st December 2019, Wuhan, China has officially reported the first case of severe acute respiratory syndrome coronavirus (SARS-CoV) to WHO. Which was named as COVID-19 by WHO on 11 February 2020.[1] After China, now COVID-19 is spreading all over the world in about 212 countries and territories. More than 3.5 million cases of COVID-19 and 250,000 deaths have been reported to WHO till 7 May 2020.[2] In India, over 46008 active, 22454 recovered, 2293 death, and 1 migrated case (a total of 70756 cases) has been reported till 12th May, 2020.[3]

The use of preventive measures such as social distancing, personal hygiene, use of personal protective equipment, and social awareness plays an important role as to prevent the spread of COVID-19.[4] Despite the use of preventive measures, appropriate medical care, symptomatic treatment, and supportive care are an important management option. Several agents such as antiviral drug, immunomodulating

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biologicals, and hydroxychloroquine proposed to have efficacy against COVID-19.[5] Till now, Remdesivir of Gilead is the first antiviral drug has been approved by Japan for the treatment of COVID-19.[6,7]

The objective of this study is to review the currently registered clinical studies in Clinical Trials Registry-India. The study provides the overall summary and insight into treatment strategies, diagnostic tools, and preventive strategies for COVID-19.

2. Materials and Methods

The Institutional Ethics Committee approval was not required for the conduct of the study. All the clinical trials (including clinical studies) registered in Clinical Trials Registry-India ((ctri.nic.in) between 31 March 2020 to 11th May 2020 were reviewed and analyzed. The registered studies were searched in the "Trial Search" option with keywords such as "COVID-19", "Corona Virus", "SARS-CoV2", and "2019 nCoV". The studies mentioned any of the search keywords in their study title or objective or inclusion criteria were selected for the study. The studies/trials were first categorized in an interventional and observational study and further analysis was done over study design, approval status, subject type to be recruited, recruitment status, etc.

3. Results

A total of 57 trials over COVID-19 have been registered in CTRI within the last three months (i.e. 1st March 2020 to 11th May 2020). The majority of registered clinical trials/studies are from New Delhi followed by Maharashtra and Uttar Pradesh (Figure 1). These trials include 40 interventional trials and 17 clinical studies. The interventional studies include the drug, biologics, ayurvedic, homeopathic, diagnostic, nutritional, and process of care change (Figure 2). The interventions registered for trials are (a) drug includes Hydroxychloroquine (HCQ), Imatinib, Ivermectin, Ciclesonide, Niclosamide (b) biologics include Convalescent plasma, BCG (c) ayurvedic include Kashaya, ZingiVir H, MyVir tablets, Dabur Chyawanprash, Shanshamani Vati, Yashtimadhu tablet, Guduchi tablet (d) homeopathic include Cadamba drug therapy, Arsenic Album, Bryonia Alba, Gelsemium, Antimonium Tartaricum, Crotalus Horridus (e) diagnostic include Chest X-Ray Artificial Intelligence Module, CT - Scan of Thorax Artificial Intelligence Module, Voice Sampling Artificial Intelligence Module (f) nutritional include SSV formulation and (g) process of care change include Povidone Iodine, Lowest driving pressure guided PEEP. Under trials, these interventions administered either alone or in combination with other drugs and compared with placebo (If applicable), the standard of care, or supportive care (Table 1).

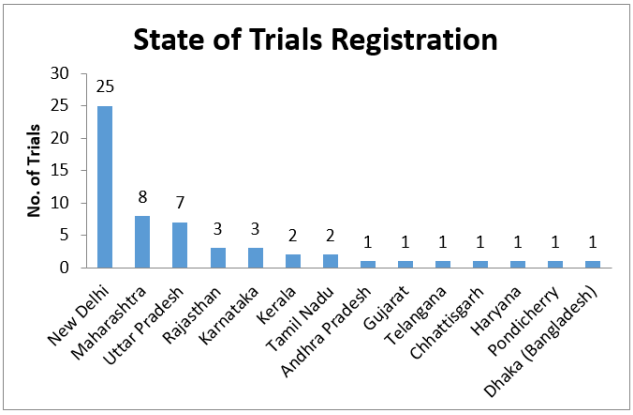

Fig. 1: State of trials registration

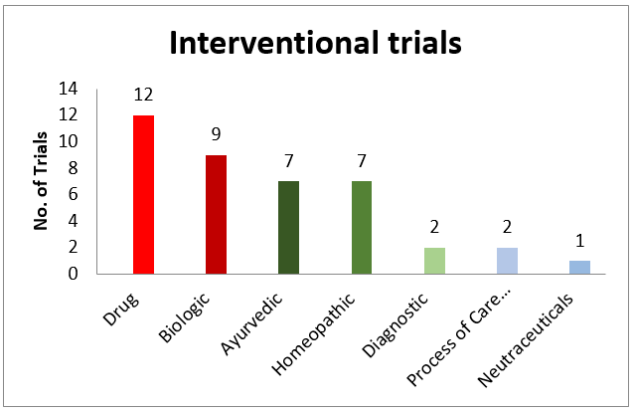

Fig. 2: Interventional trial

Most of the observational studies are the prospective type of studies including healthy as well as COVID-19 patients to generate impactful evidence over health, condition diagnosis, prevention, treatment outcomes, and mental status (anxiety, fear of COVID-19) (Table 2).

Table 1: Interventional studies

Interventional-Drug Reg. ID CTRI/2020/.....	Intervention	Randomization	Blinding	Subject	Sample Size	Recruit-ment Status	Estimate Duration (Months)	Phase	State
03/024402	Grp A: Hydroxy Chloroquine Grp B: Hydroxy Chloroquine (HCQ)-ICMR regimen	Yes	Open	Healthy Human Volunteers	500	Not Yet	3	III	Kerala
04/024479	Grp A: Chloroquin Phasphate Grp B: Standard care	Yes	Open	COVID-19 Patients	32	Not Yet	6	NA	Karnataka
04/024806	Grp A: Imantinib Oral Drug Grp B: Standard care	Yes	Open	COVID-19 Patients	100	Open	2	II	New Delhi
04/024729	Grp A: Topical Nasal 0.03% chloroquine eye drops Grp B: Standard Care	Other	Open	COVID-19 Patients	60	Not Yet	6	II	New Delhi
04/024904	Grp A: HCQ high dose (HCQh) ,Hydroxychloroquine sulfate (HCQs) Grp B: HCQ AZT	Yes	Double	COVID-19 Patients	300	Not Yet	12	III	Uttar Pradesh
04/024858	Grp A: Ivermectin Grp B: Standard treatment as per hospital protocol for COVID 19	No	Open	COVID-19 Patients	50	Not yet	12	NA	New Delhi
04/024948	Grp A: Ciclesonide, Hydroxychloroquine, Ivermectin Grp B: Satandard care of treatment	Yes	NA	COVID-19 Patients	120	Not Yet	6	II	New Delhi
04/024949	Grp A: Niclosamide Grp B: Satandard care of treatment	Yes	NA	COVID-19 Patients	48	Not yet	3	II	New Delhi

Continued on next page

Table 1 continued

05/025067	Grp A: Hydroxychloroquine along with Standard care Personal protective equipment Grp B: Standard care Personal protective equipment	Yes	Open	COVID-19 Patients	10990	Not Yet	12	NA	New Delhi
04/024773	Grp A: chloroquine or hydroxychloroquine Grp B: Local standard of care, Lopinavir with Ritonavir (ditto) plus Interferon, Lopinavir with Ritonavir (orally twice daily for 14 days) , Remdesivir	Yes	Open	COVID-19 Patients	7000(Global), 1500 (India)	Open	12	III	Maharashtra
05/024959	Grp A: Best supportive care with Itolizumab Grp B: Standard of care	Yes	Open	COVID-19 Patients	30	Not Yet	3	II	Maharashtra
05/025022	Grp A: Hydrooxychloroquine Grp B: Symptomatic treatment	Other	Open	COVID-19 Patients	166	Not Yet	12	II	New Delhi
Interventional-Biologics									
04/024804	Grp A: Convalescent plasma Grp B: NA	Single arm	NA	COVID-19 Patients	10	Not Yet	3	II	Karnataka
04/024915	Grp A: Convalescent Plasma Grp B: Satandard care of treatment	Yes	Open	COVID-19 Patients	100	Not Yet	24	II	New Delhi
05/025013	Grp A: BCG plus standard of care as suggested by DCGI Grp B: Saline plus standard of care	Yes	Single	COVID-19 Patients	60	Not yet	3	II	Maharashtra

Continued on next page

Table 1 continued

04/024749	Grp A: Recombinant BCG vaccine, VPM1002 Grp B: Saline plus standard of care	Yes	Triple	COVID-19 Patients	5946	Not Yet	12	III	Maharashtra
04/024706	Grp A: Convalescent Plasma with Supportive Care Grp B: Random donor Plasma with Supportive Care	Yes	Open	COVID-19 Patients	20	Not Yet	3	II	New Delhi
04/024846	Grp A: Suspension of heat killed (autoclaved) Mycobacterium w Grp B: Placebo	Yes	Triple	COVID-19 Patients	40	Not Yet	6	NA	Gujarat
04/024833	Grp A: BCG-Denmark (Green Signal) Grp B: Placebo	Yes	Triple Blind	Healthy Human Volunteers	1826	Not Yet	12	NA	Pondicherry
04/024775	Grp A: Convalescent plasma Grp B: Usual care for COVID-19 disease	Yes	NA	COVID-19 Patients	52	Not Yet	6	II	New Delhi
05/024989	Grp A: NA (Genetic Mutation Identification) Grp B: NA	Other	NA	COVID-19 Patients	200	Not Yet	24	NA	Telangana
Interventional-Ayurvedic									
04/024882	Grp A: kashaya (Dicoction) of Tinospora cordifolia Grp B: Standard Care	NA	NA	COVID-19 Patients	30	Not Yet	12	II	Haryana
04/024883	Grp A: ZingiVir H Grp B: NA	Other	Outcome Assessor	COVID-19 Patients	112	Open	6	IV	Kerala
5/024967	Grp A: MyVir tablets Grp B: Standard treatment as per hospital protocol for COVID 19	Single arm	NA	COVID-19 Patients	30	Not Yet	6	IV	Karnataka

Continued on next page

Table 1 continued

05/024981	Grp A: Dabur Chyawanprash Grp B: Milk	Yes	Open	Healthy Human Volunteer	600	Not Yet	8	NA	Rajasthan
05/025069	Grp A: Shanshamani Vati or Sudarshana Ghanavati or Ashwagandha Grp B: NA	Single arm	Open	Healthy Human Volunteers	1324	Not Yet	3	III	New Delhi
05/025093	Grp A: Yashtimadhu tablet Grp B: NA	Other	NA	Healthy Human Volunteers	1200	Not Yet	1 Month, 15 days	II /III	Andhra Pradesh
05/025088	Grp A: Guduchi tablet Grp B: Nil	Yes	NA	Healthy Human Volunteers	1200	Not Yet	6	I/II	Andhra Pradesh
Interventional Homeopathic									
04/024857	Homeopathy Medicines - Ars Alb, Camphora, Bryonia Alba, Helleborus niger, Justicia Adhatoda.	Yes	Open	COVID-19 Patients	100	Not Yet	1	II	Maharashtra
04/024905	Grp A: Homoeopathic Medicine: Arsenic Album, Bryonia Alba, Gelsemium, Antimonium Tartaricum, Crotalus Horridus Grp B: Placebo	Yes	Single	COVID-19 Patients	100	Not Yet	3	III	Uttar Pradesh
04/024947	Grp A: Cadamba drug therapy Grp B: NA	Yes	NA	COVID-19 Patients	100	Not Yet	3	III	Maharashtra
04/024925	Grp A: Homoeopathic Medicine Grp B: Placebo	Yes	Open	COVID-19 Patients	1000	Not Yet	2	II	Maharashtra

Continued on next page

Table 1 continued

04/024926	Grp A: Homoeopathic Medicine: Arsenic Album, Bryonia Alba, Gelsemium, Antimonium Tartaricum, Crotalus Horridus Grp B: NA	Single arm	Single	COVID-19 Patients	100	Not Yet	2	III	Uttar Pradesh
05/024969	Grp A: Homoeopathic medicine Grp B: Placebo	Yes	Open	COVID-19 Patients	100	Not Yet	3	III	Uttar Pradesh
05/024986	Grp A:Homoeopathic medicine Arsenic album 30c	Single arm	NA	COVID-19 Patients	10000	Not Yet	6	NA	New Delhi
Interventional-Diagnostic									
04/024776	Grp A: Chest X-Ray Artificial Intelligence Module, CT - Scan of THORAX Artificial Intelligence Module, Voice Sampling Artificial Intelligence Module Grp B: Normal subjects Chest X-Ray , CT-Scan Thorax and Voice sampling	No	NA	COVID-19 Patients	1650	Open	3.5	NA	Rajasthan
05/024983	Grp A: Topical Lignocaine Grp B: NA	Single arm	NA	COVID-19 Patients	30	Not Yet	1	NA	New Delhi
Interventional-Process of care change									
05/024962	Grp A: Povidone Iodine Grp B: SALINE plus STANDARD of CARE as suggested by DCGI	Yes	NA	COVID-19 Patients	96	Not Yet	3	NA	Andhra Pradesh

Continued on next page

Table 1 continued

05/025071	Grp A: Lowest driving pressure guided PEEP Grp B: Conventional lung protective ventilation strategy(ARDSnet protocol)	Yes	Single	COVID-19 Patients	40	Not Yet	12	III	New Delhi
Interventional- Nutraceuticals									
04/024659	Grp A: SSV formulation Grp B: NA	Single arm	NA	COVID-19 Patients	30	NA	6	III	Maharashtra

Table 2: Observational studies

Reg. ID CTRI/2020/.....	Purpose	Study Design	Subject	Sample Size	Recruiment Status	Estimate Duration (Months)	State
Observational Studies-Retrospective							
04/024473	COVID-19 Registry and Validation of C2D2 (Critical Care Data Dictionary)	Retrospective data collection	COVID-19 Patients	50000	Not Yet	256 M, 30 days	New Delhi
04/024697	Formulation of a Clinical databank by consolidation of Indian data.	Retrospective data collection	COVID-19 Patients	100000	Not Yet	24	New Delhi
Observational Studies-Prospective							
04/024442	Screening for symptoms of COVID-19	Follow up study	COVID-19 Patients	5000	Not Yet	4	New Delhi
04/024413	Assessment of Knowledge, attitudes, and fear of COVID-19	Cross Sectional Study	Healthy Human Volunteers	1000	NA*	14 days	Dhaka Bangladesh
04/024482	evaluating the prophylactic efficacy of different regimens against SARS-CoV2 infection (COVID-2019) in asymptomatic health care workers	Virtual Registry Study	Healthy Human Volunteers	10000	Open	24	Tamil Nadu
04/024784	Assessment of Anxiety and depression during covid-19	Cross Sectional Study	Healthy Human Volunteers	1000	Not Yet	12	New Delhi
04/024636	Objective clinical scoring system to rule out COVID-19 with high sensitivity	Cohort Study	COVID-19 Patients	1000	Not Yet	3	Rajasthan
04/024805	Impact of Covid-19 pandemic on practice pattern of Indian urologists	Survey	Healthy Human Volunteers	160	Not Yet	7 days	Uttar Pradesh
04/024772	Comparison of suspected with confirmed cases of COVID-19	Cohort Study	COVID-19 Patients	90	Not Yet	2	New Delhi

Continued on next page

Table 2 continued

04/024859	Clinical characteristics and treatment Outcome of COVID-19 Patients	Cross Sectional Study	COVID-19 Patients	1000	Not Yet	12	New Delhi
05/025010	Hydroxychloroquine prophylaxis in Covid 19 infection	Follow up Study	Healthy Human Volunteers	2000	Not Yet	6	New Delhi
04/024914	Characteristics of seriously ill COVID-19 patients	Cohort Study	COVID-19 Patients	60	Not Yet	3	New Delhi
05/024982	Effects of using hydroxychloro-quine and azithromycin in the treatment of confirmed COVID-19 positive patients	Cross Sectional Study	COVID-19 Patients	50	Not Yet	6	Chhattisgarh
05/025041	Radiographic findings and their temporal changes in COVID-19 positive patient	Cohort Study	COVID-19 Patients	200	Not Yet	12	New Delhi
05/025070	Issues and challenges in cancer patients on active treatment during the COVID-19	Cross Sectional Study	COVID-19 Patients	150	Not Yet	12	New Delhi
05/025089	Effect of Hydrox-ychloroquine on QTc Interval	Cohort Study	Healthy Human Volunteers	50	Open	6	Uttar Pradesh
05/025091	Knowledge status of public about COVID 19 disease prevention and control	Cross Sectional Study	Healthy Human Volunteers	125	Not Yet	3	Tamil Nadu

⁎*A study from Bangladesh registered in CTRI but not recruiting the subjects from India*

4. Discussion

The CTRI launched on 20th July 2007 is directed by the ICMR-National Institute of Medical Statistics, New Delhi, India. The CTRI is an online, free of cost and searchable platform for the registering all clinical studies prospective being conducted in India and was made mandatory by 1st April 2018.[8] In the current pandemic situation of COVID-19, the discovery and development of a new drug is not an easy task. As the number of COVID-19 cases increasing progressively, the preventive medical option is in high demand. According to WHO, 2118 clinical trials have been registered on WHO international clinical trials registry during COVID-19 pandemic from all over the world and in this context China is on top.[9] Despite, this much number of clinical trials registration all over the world, not a single drug (except Gilead-Remdesivir) is approved for the treatment of COVID-19.[10]

In India, 57 trials have been registered in CTRI for COVID-19 diagnosis, treatment, prevention and to assess treatment outcomes of existing therapies. Fourteen out of 40 interventional trials are in phase III and above of clinical trials and surprisingly, only two of these trials are open for recruitment. The average duration of completion of interventional trials is 6.3 months.

4.1. Treatment strategies

4.1.1. Anti-malarial

HCQ is an anti-malarial drug, which had been proved as having antiviral activity.[11] In a study from China also stated that the HCQ may be a potential treatment option for COVID-19.[12] In CTRI, seven drug trials investigating the effectiveness of Hydroxychloroquine (HCQ) for the treatment of COVID-19.

4.1.2. Antiprotozoal

In CTRI, Ivermectin and Niclosamide two antiprotozoal drugs have been registered to investigate treatment effectiveness for COVID-19. In the 1970s, Ivermectine was recognized as 'Wonder Drug" because of its wide application in human and animal health. A study demonstrated the antiviral activity of ivermectin in it inhibit bovine herpesvirus 1 DNA polymerase nuclear import and interferes with viral replication.[13] Niclosamide is an antiprotozoal drug having wide antiviral application; effectiveness as COVID-19 treatment could be expected.[14]

4.1.3. Antiviral

None of the antiviral drugs has been registered in CTRI for COVID-19 treatment. However, in the global clinical trials database, a large number of clinical trials have been registered to assess their effectiveness for the treatment of COVID-19. These trials include lopinavir/ritonavir, sofosbuvir/ledipasvir, favipiravir, umifenovir, triazavirin, baloxavir marboxil, azvudine, darunavir/cobicistat, sofosbuvir/daclatasvir, and emtricitabine/tenofovir as investigational drug.[9] Remdesivir is a broad-spectrum antiviral drug, had been used for the treatment of Marburg and Ebola viruses. A recent study has found Remdesivir having potential efficacy against COVID-19.[15]

4.1.4. Anticancer

Imatinib and Itolizumab two anticancer drugs have been registered in CTRI. The US National Library of Medicine clinical trial database (ClinicalTrials.gov) has registered a randomized, phase 2 clinical trial for investigating the effectiveness of imatinib mesylate as early treatment of COVID-19.[16] Itolizumab is humanized IgG1 monoclonal antibody which selectively targets CD6. A phase 1 clinical trial to evaluate the safety, effectiveness and clinical activity of Itolizumab in subjects with moderate-to-severe uncontrolled asthma has been registered in ClinicalTrials.gov database.[17]

4.1.5. Biologics

A total of nine trials have been registered in CTRI including four Convalescent plasma, three BCG vaccine, one suspension of heat-killed (autoclaved) Mycobacterium w, and one of genetic mutation identification. Convalescent plasma (or immune plasma) is collected from COVID-19 infected and recovered individual (i.e., human antieSARS-CoV-2 plasma); transfused into infected patients as post-exposure prophylaxis.[18] Several studies reported convalescent plasma as an effective preventive measure against COVID-19.[19,20] BCG vaccine has beneficial imprecise (off-target) effects on the immune system that defend against a wide range of other infections and are used routinely to treat bladder cancer. Several studies and trials are underway to generate evidence of use in COVID-19 prevention.[21,22]

4.1.6. Ayurvedic

A total of seven studies have been registered for Ayurvedic drugs which include kashaya (Decoction) of Tinospora cordifolia, ZingiVir H, MyVir tablets, Dabur Chyawanprash, Shanshamani Vati or Sudarshana Ghanavati or Ashwagandha, Yashtimadhu tablet, Guduchi tablet. These Ayurvedic formulations are consisting of polyherbal drug which is used to strengthen the immune system and fight against infectious diseases. Enough clinical evidence is not available for the use of Ayurvedic drugs against COVID-19. However, Ministry of AYUSH published guidelines for safety precaution against COVID-19.[23]

4.1.7. Homeopathic

A total of four trials have been registered of homeopathic medicine Arsenicum album-30 is a common prescription medicine for respiratory infection, flu-like illness in daily practice which believed to be effective against COVID-

19.[24] One trial is of Cadamba, a medically potent plant having wide application in infectious as well as other disease and health condition.[25] The use of Cadamba against COVID-19 is suspicious.

4.1.8. Diagnosis

The Real-Time Reverse Transcriptase (RT)-PCR Diagnostic tool detects the COVID-19 virus in upper and lower respiratory sampling.[26] Now, CTRI registered a trial investigating the diagnostic tool such as a chest X-ray artificial intelligence module, CT-scan of thorax artificial intelligence module, in combination with voice sampling artificial intelligence module which may provide the better diagnosis. Another trial registered to asses decreases in the gag reflex while sampling for Covid-19 topical lignocaine.

4.1.9. Neutraceutical

A study has been registered in CTRI to investigate the immunity enhancing effect of SSV formulation (neutraceuticals) in COVID-19 patients.

4.2. Observational studies

A total of 17 observational (two retrospective and fifteen prospective) studies have been registered in CTRI. These COVID-19 studies have been designed for various objectives such as screening for symptoms, assessment of the knowledge, attitudes, and fear to evaluate the prophylactic efficacy of different regimens in asymptomatic health care workers, anxiety and depression during COVID-19, clinical characteristics and treatment outcome, hydroxychloroquine prophylaxis, radiographic findings and their temporal changes, knowledge status of the public.

The availability of new treatment modality against COVID-19 depends on the successful completion of the registered trial. Various factor affecting the completion of these trials such as COVID-19 itself a rapidly spreading infectious disease, large sample size, availability of research facilities/resources, and involvement of trained and skilled research staff, etc. may affect recruitment of subject and completion of trials resulting delay in trials result or outcomes.

However, the fast track approval of clinical trials, effective study design, making informed consent more "inform", planning and scientific consideration over sample size, development of data safety monitoring board to supervise and ensure trial participants safety may enforce the successfulness of trials completion.[27]

After China, the world is suffering from the COVID-19 outbreak. Till the availability of an impactful medical weapon against COVID-19, standard care, supportive care, symptomatic treatment, personal hygiene, social distancing, etc. are the considerable tools helpful in combat against COVID-19. Now, India is almost completing three stages lockdown of almost 54 days (25^{th} March to 17^{th} May 2020) followed by an announcement of the 4^{th} stage lockdown on 12^{th} May 2020 to break the chain of COVID-19 infection. Even though, the cases of COVID-19 are increasing vigorously in Maharashtra (on top). This pandemic situation affected health, lifestyle, job, and economy to a great extent.

5. Conclusion

The world is combating against the COVID-19 outbreak. The availability of new health intervention against COVID-19 needs the more scientific, and collaborative center of attention towards drug development and clinical trials for COVID-19.

6. Source of Funding

None.

7. Conflict of Interest

None.

8. Acknowledgement

Nil.

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