

Clinical trials in which treatment is Moxibustion

Kire Stojkovski¹, Evgenija Dameska-Stojkovska², Vladimir Stojkovski³, Mihail Petrov Mihaylov⁴

1. PSI-CRO, Sofia R. Bulgaria
2. UMBAL St Anna, Sofia, R. Bulgaria
3. GOB 8 September, Skopje, Republic of N. Macedonia
4. Skin Line, Sofia, R. Bulgaria

DOI:

Abstract

Moxibustion is one of the most used treatments that are part of Traditional Chinese Medicine. The moxibustion treatment involves herbal materials called moxa that is placed on different points of the human body, in most cases it is placed on ACU points, which is stimulating the qi energy circulation in the patient's body, as it is explained in the materials and books that are providing information regarding Traditional Chinese Medicine. There are couple of known practices in moxibustion, there is a direct method that can cause a little scar on the treated point, there is direct method, in which the moxa is taken out prior to the forming of the scar, and there is third method which is indirect method, this method is used with previously prepared moxa which is held near the acupuncture point, and it is warming up the acupuncture point. There are some other various ways of using moxibustion. One of them is placing the moxa on acupuncture needle and inserting the acupuncture needle in the patient's body, and as expected there are a new modern way of placing the moxas on the patient's body. Most of the clinical trials organized to prove the efficacy of moxibustion are with low quality and does not provide a lot of information about this method of treatment. Most of the Clinical trials are organized in People's Republic of China, however there are organized clinical trials for this method of treatment in other countries. Possible Adverse Events that can occur during this treatment are burns, infection, pain, and nausea. The number of Adverse Events is not that high, that is one of the reasons for using this method as a treatment for a lot of cases by the practitioners, practicing Traditional Chinese Medicine. More clinical trials are needed so the efficacy of this method can be proven, and this method can be accepted as a treatment in the whole world.

Key Words: Moxibustion, Moxa, Acupuncture, Traditional Chinese Medicine, Qi energy

Introduction

The aim of this article is to provide information regarding the number of organized clinical trials in which treatment with moxibustion is the main intervention. What type of clinical trials were organized, were the clinical trials were organized only in People's Republic of China or there are some other countries in which this kind of clinical trials were organized, and for how many of them results are available after they were completed. Also, in this article information regarding the treated condition with moxibustion will be provided.

Organized clinical trials in which main treatment is moxibustion are a great opportunity, for both eastern and western medicine for collecting new information regarding relevant disease, and for providing new ways of treatment for the targeted disease. It is also good for the patients because new possible treatment for some disease is examined. If the clinical trial is successful at the end the biggest benefit will be for the patients.

The organized clinical trials in which the treatment is moxibustion are from Interventional and Observational type.

In the clinical trials of interventional type, the patients are receiving the treatment with moxibustion, for treatment of relevant disease. Depending on the clinical trials in this group of clinical trials the patients are receiving a treatment of moxibustion, or combination of moxibustion and some other previously approved treatment from both eastern and western medicine. In the clinical trials of observational type, the safety of moxibustion is examined, however there are some trials in which also safety and efficacy is examined. In this type of clinical trials, relevant information about new possible Adverse Events, or new possible conditions is collected.

The most proper indications of moxibustion therapy are colitis, malposition and diarrhea; the common proper indications are dysmenorrhoea, urinary incontinence, asthma, knee osteoarthritis, soft tissue injury, temporomandibular joint disturbance syndrome, heel pain, urinary retention, and herpes zoster. [1] [2]

One of the most known main buffers of moxas are ginger and garlic. The garlic and ginger had been put on the evaporating dish for experiment and had confirmed that allicin and gingerol, their active ingredients, could act on the body by heat to give the therapeutic effects. [3] The extracts of moxa combustion ashes show a strong ability of anti-free radicals. [4]

The positive aspect of moxibustion is that it is available, it is not expensive, and almost all of the patients can be treated with this method. For this treatment there are only few contra indications, and it is safety to be used for both children and adult. The one negative condition is the scars that can occur during this treatment. However, there are some believes in Traditional Chinese Medicine that if there is scar because of moxibustion, the disease will be cured.

Possible adverse events that can occur during moxibustion are some local allergies, some sensitivities because of the smoke, and possibility of some lung condition. However, these adverse events occur very rarely.

Compared to acupuncture as a part of traditional Chinese medicine, the moxibustion is studied much less. It can be proven by the number of organized clinical trials involving both the methods as an intervention. Also, acupuncture is more popular in between the people, and it is used a lot more compared to moxibustion.

If the efficacy of moxibustion can be proven, the number of patients that are treated with moxibustion can become higher.

Materials and methods

The research of this study includes review of reported and published information about the Clinical Trials available on <https://clinicaltrials.gov/> which is the biggest and the most reliable source for information of this kind. It is a database web page of privately and publicly funded clinical studies conducted all around the world.

ClinicalTrials.gov, is a great resource of information about clinical studies and their results, together with specialized search tools, provides a unique window into the clinical research enterprise, which includes all ongoing, initiated, completed or terminated clinical studies.

The number of researchers that use database information to assess research reporting practices, or to characterize the clinical research enterprise recently is increasing. [5]

The filters that were used to get the results are:

1. Intervention/ treatment used in the Clinical Trial is selected Moxibustion,

The used filter will provide all the needed information regarding clinical trials in which moxibustion is the main intervention. Since the number of clinical trials is not that high, another filter was not used.

The information were received regarding the number of organized clinical trials, first organized and reported clinical trial, the type of the clinical trials, the phase in which the clinical trial is conducted, the countries in which the clinical trials took place, the number of clinical trials that are accepting children as potential patients, and also what was the treated condition with moxibustion.

After getting the results, some of the results are sorted into diagrams for better visualization.

Result & discussion

According to the statistical analysis and the data reported on <https://clinicaltrials.gov/>, overall, there are 105 reported clinical trials in which the intervention is moxibustion. The

first reported clinical trial in which intervention is moxibustion is dated from September 1999. On the first clinical trial chronic diarrhea was treated.

This number is low, and the number prior to the study was expected to be higher, knowing the desire of the scientist and medical persons from People’s Republic of China to prove the safety and efficacy of this method as a treatment. However, the number can be this low due to the fact that the organizers and the investigators that are part of clinical trials like this are choosing some different platforms for reporting results from clinical trials. This assumption must be additionally investigated. The opinion of our team is that using different platform for reporting this kind of clinical trials is not good, because <https://clinicaltrials.gov/> is one of the most used platforms for reporting data from clinical trials. If the investigators are insisting to use domestic platform for reporting this kind of trials, it is good to also report them on some other platform so the information can be available for everyone both internal and external from the country that it is conducted. Also, in the past years the covid 19 pandemic took place, and that pandemic has made the number of potential clinical trials to be lower than expected.

From the available data it can be seen that from all the 105 reported clinical trials, 99 are from interventional type and 6 are from observational type.

These numbers are expected, because in most of the cases the number of interventional clinical trials is higher compared to the number of observational clinical trials. However, moxibustion as procedure is giving more opportunities for organizing observational clinical trials because it can be observed how is conducted clinical trial, which is combination of couple of treatment methods, and one of the methods is moxibustion.

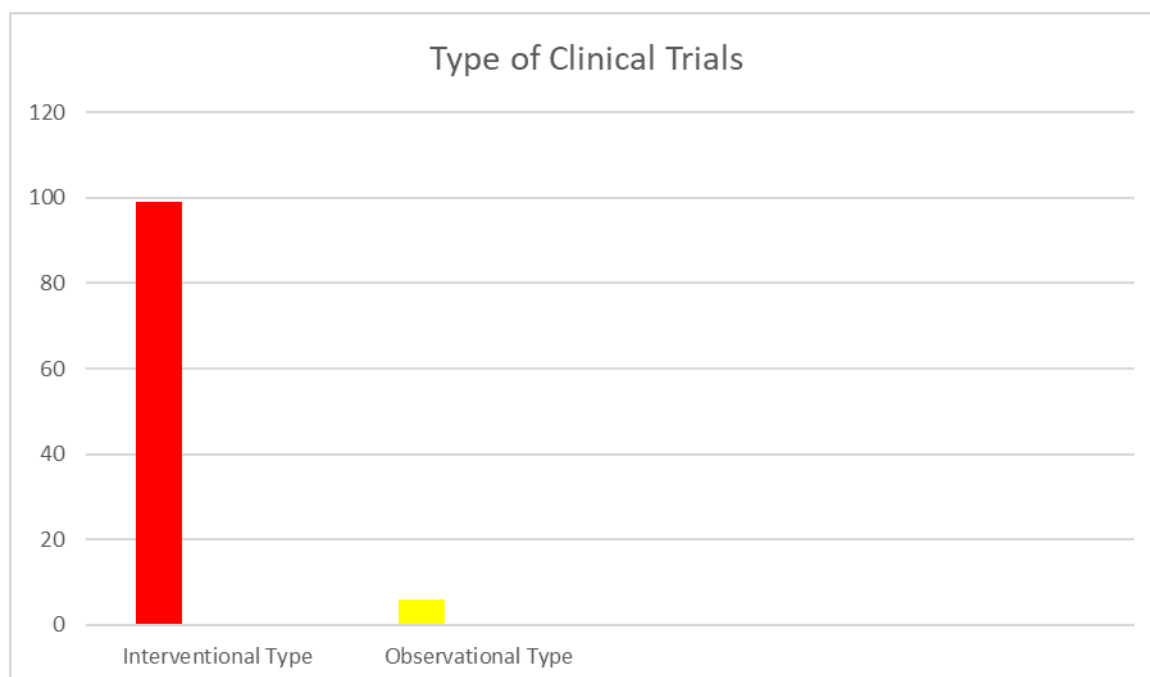


Chart 1. Type of Clinical Trials

Regarding the study phase in which the clinical trials are conducted, 3 of the trials are in phase 1, 11 are in phase 2, 6 are in phase 3. There are not any clinical trials in phase 4, and for the rest of the clinical trials the phase is not available at the moment.

The highest number of clinical trials do not have phase of the study reported at the moment. This is showing that the organized clinical trials for moxibustion are with low quality, and in future clinical trials with higher quality should be organized. However there is a possibility that the phase of the trial is not reported because the data is reported on some other platforms for reporting clinical trials, but this assumption needs to be examined.

From the reported clinical trials phases the highest number is in phase 2, prior to the research it was expected that studies in phase 3 will be the most, however the number is higher in phase 2 and in this phase the efficacy of the moxibustion is determined.

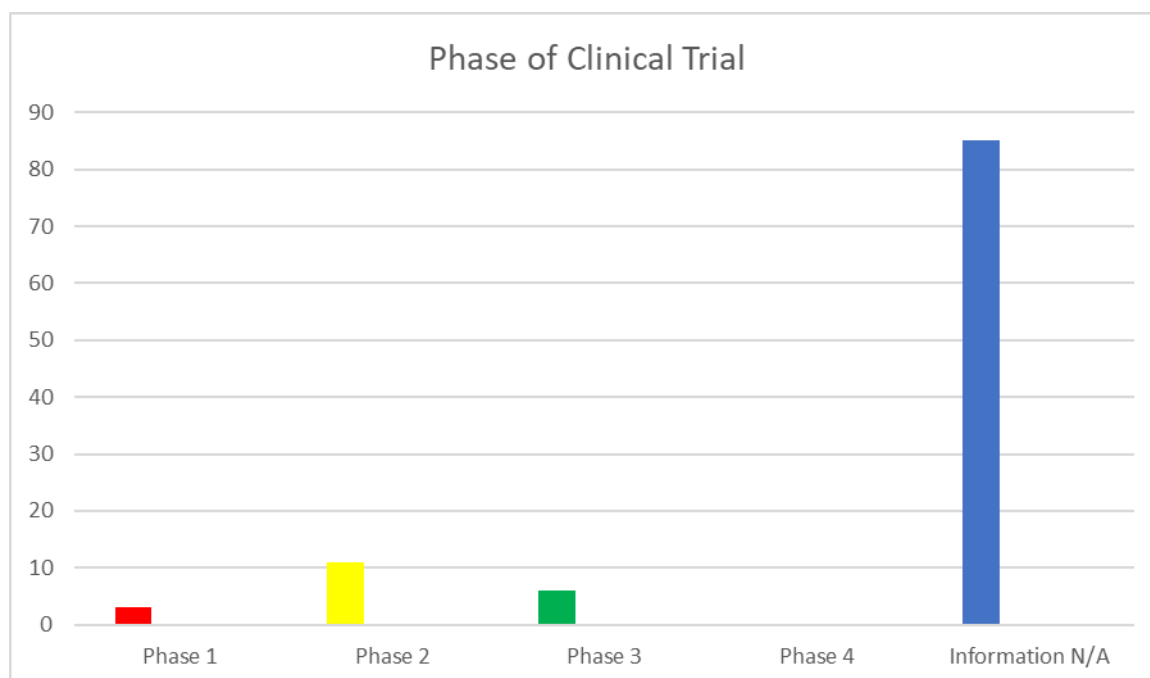


Chart 2. Phases of clinical trials

Regarding countries in which moxibustion clinical trials are conducted, the highest number as expected is in People's Republic of China, 70 of the reported clinical trials are conducted in People's Republic of China, 8 of the reported clinical trials are conducted in USA, 8 are in Republic of Korea, 3 are in United Kingdom, 2 are in Switzerland and there is 1 each in France, Vietnam, and Turkey.

This numbers are expected, since moxibustion mostly is used in People's Republic of China. The fact that there are 8 moxibustion clinical trials in USA is encouraging. Also the numbers in the other countries, even though they are low are showing that there is some interest in Moxibustion as a therapeutical procedure.

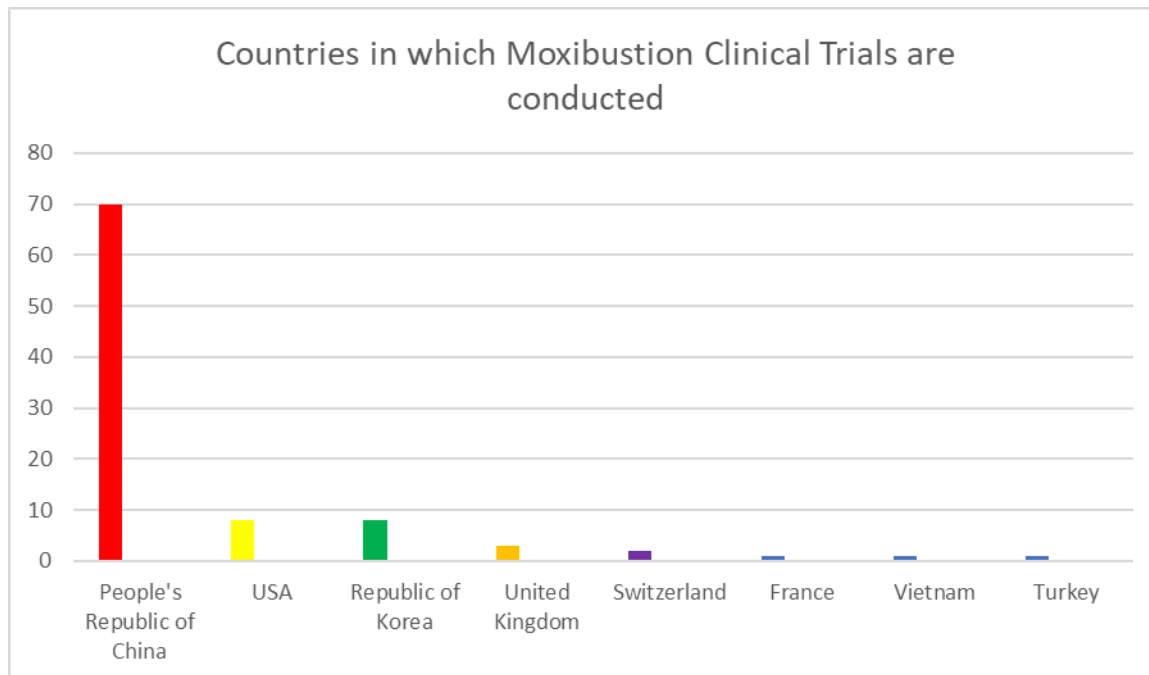


Chart 3. Countries in which Moxibustion Clinical Trials are conducted

Regarding the numbers of clinical trials and the ages of potential patients that can be part of the clinical trials, 91 of the clinical trials are accepting only adult population, and 14 of the clinical trials are accepting both adult and children as patients in the clinical trials.

These numbers are showing that the moxibustion as procedure is determined to be safety used for treatment of both adults and children population, depending on the treated condition.

Regarding the conditions treated with moxibustion that are part of clinical trials, the highest number of treated conditions is the treatment of Crohn disease and ulcerative colitis with 12 clinical trials for these conditions, 9 of the clinical trials are related to symptoms that appear at cancer patients, 7 of the clinical trials are related to management of pain due to a different reason, 6 of the clinical trials are related to osteoarthritis of the knee, 5 of the clinical trials are related to COPD and Asthma, there are 5 clinical trials related to allergic rhinitis, 4 are related to obesity, there are also 4 clinical trials for treatment of some not expected symptoms at HIV positive patients, reported are 3 trials each for conditions as infertility, diabetic peripheral neuropathy, breach position of fetus during pregnancy, and insomnia. Reported are 2 trials each for conditions as constipation, tinnitus, facial nerve paralysis, irritable bowel syndrome, hypotension, chronic stable angina pectoris, conditions that can appear after stroke, chronic fatigue syndrome, depression, and general improvement of health. Reported are 1 trial for each condition as coronary artery disease, covid 19 positive patients, rheumatoid arthritis, traumatic spinal cord injury, fever, primary dysmenorrhea, over reactive bladder, cystitis, issues during ovulation, stress urinary incontinency,

demyelinating diseases of the Central Nervous System, Polycystic Ovary Syndrome, hyperlipidemia, dry eyes, and benign hyperplasia of the prostate.

For 3 of the organized clinical trials the information about the treated or observed condition is not available.

Most of the treated condition are expected, however there are couple of conditions like coronary artery disease, chronic angina pectoris and traumatic spinal cord injury that were not expected to be treated with moxibustion. Even though it is really good that the practitioners are trying their best to provide new indications that can be treated with this treatment.

In future is expected that the scope of indications will be expanded.

In the chart related to conditions treated with moxibustion only the conditions for which up to 4 clinical trials were conducted will be shown.

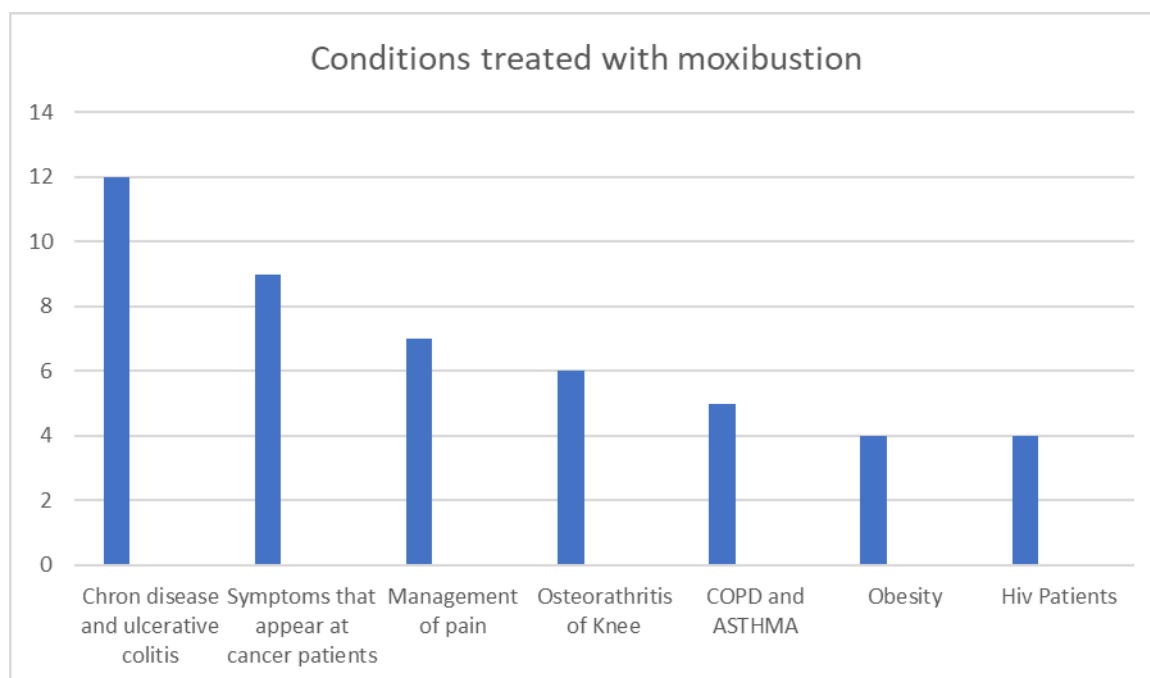


Chart 4.

Conditions treated with moxibustion

Conclusion

The study is based on a data about the Clinical Trials available on <https://clinicaltrials.gov/> which is the biggest and the most reliable source for information of this kind. It is a database web page of privately and publicly funded clinical studies conducted all around the world.

From the available reported data, it can be seen that the number of clinical trials in which main treatment is moxibustion is low and in future is expected to become higher.

From the available data it can be seen that the quality of the organized clinical trials is not on high level, or the reporting of the clinical trials is not on high level.

From all the reported clinical trials only for 2 of them there are results provided.

For one of the studies the result is: No significant effects of moxibustion were found in correcting the breech position in primiparous and parous women after their 33rd gestational week. [6] For the second study for which result is available the result is positive regarding treatment with moxibustion, This small study suggests acu/moxa is an acceptable adjunct to usual care for cancer survivors with lymphoedema. Further rigorous research is warranted to explore the effectiveness of acu/moxa in reducing the symptom burden. [7]

Overall, the number of reported clinical trials with moxibustion is low, it is good that the clinical trials are organized in more countries not just in People's Republic of China, overall worldwide clinical trials have been organized in 8 countries. It means that the other countries are also accepting this kind of interventions as a treatment for different diseases. Also, since there are studies that are also accepting children as potential patients it is showing that the intervention is safety to be used with almost all of the people. Overall reported are 37 conditions that are treated with moxibustion in clinical trials. Even though probably there won't be positive result for all of the reported condition, it is good that scientists and medical practitioners are looking to find new way of treatment for different conditions. This can be beneficial for the patients and the health care system if at some point it can become part of the health care systems in different countries, since this is not an expansive procedure, and medical practitioners can be trained to practice this procedure.

In future it is expected that the quality of this kind of clinical trials to become higher, and the results will be reported, so the medical practitioners will have more information regarding choosing different interventions for treatment of different conditions. With more organized clinical trials, more scientific facts regarding Traditional Chinese Medicine can be found.

References

1. Qinfeng H, Huangan W, Jie L, et al. Bibliometric analysis of diseases spectrum of moxibustion therapy. *Journal of Acupuncture and Tuina Science*. 2012;10(6):342–334.
2. Zhu J, Arsovska B, Kozovska K; The impact and role of the Traditional Chinese Medicine on human health; IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)e-ISSN: 2279-0853, p-ISSN: 2279-0861. Volume 17, Issue 10 Ver. 7 (October. 2018), PP 80-8
3. Ikuko N, Nobuo U. The antioxidative substance in the products of burned moxa. *Journal of the Japan Society of Acupuncture*. 1988;38(1):p. 39.
4. Hong Z, Yang M, Nong Y, et al. Composition analysis of QiAi burning ashes by HPLC. *Journal of South-Central University for Nationalities (Natural Sciences)* 2008;27(3):47–49.

5. Tse T, Fain KM, Zarin DA. How to avoid common problems when using ClinicalTrials.gov in research: 10 issues to consider. *BMJ*. 2018;361:k1452
6. Bue L, Lauszus FF. Moxibustion did not have an effect in a randomized clinical trial for version of breech position. *Dan Med J*. 2016 Feb;63(2):A5199. PMID: 26836801.
7. De Valois BA, Young TE, Melsome E. Assessing the feasibility of using acupuncture and moxibustion to improve quality of life for cancer survivors with upper body lymphoedema. *Eur J Oncol Nurs*. 2012 Jul;16(3):301-9. doi: 10.1016/j.ejon.2011.07.005. Epub 2011 Sep 13. PMID: 21917515.