CLINICAL TRAILS

Clinical Trials in Republic of North Macedonia in the period of 2018-2023.

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Abstract

Clinical trials are studies that can determinate the efficacy and the safety of new drugs, treatments, or medical devices. The trials are verification that something new is helpful for patients and it would not cause any injury or adverse event. The differentiations in the clinical trials are firstly of what is going to be examined, is it new drug, new medical procedure, or new medical device.

Another way to divide the clinical trials is depending on the phase in which the clinical trial is taking place. There are four phases of the clinical trial, The first phase is to determinate if the new way of treatment is safe, usually it is done on healthy volunteers. The goal of phase two is to be found out the right dose and effectiveness in treating diseases, usually it is done on a wide group of volunteers who have the targeted disease. The main goal of the third phase is to give answers if the new treatment can produce good results on a big group of volunteers, If the result will be better than the previous standard of care. The fourth and the final phase of the clinical trials is done after the new treatment is approved for usage. In this phase new not reported rare adverse events are investigated.

Key words: Clinical Trials, Phases of clinical trials, studies, new treatments, new medicine

Introduction

The clinical trials are examinations in which a test on new drug, new medical device, or a new medical procedure is made. Everything should be done on a voluntary basis, no participant in clinical trial should be a part of the trial against their will.

The main document in all the studies is the study protocol which is a document that defined and manage the clinical trial. In the study protocol everything that is related to the trial is written and explained. All the study protocols are written under the ICH GCP guidelines. The study protocol can be viewed as a written agreement between the

investigators, the participant, and the scientific community. The contents specify the objectives, provide the background and describe the design and organization of the trial. Every detail that explains how the trial is carried out doesn't need to be included and provided that a comprehensive manual of procedures contains such informations. The protocol serves as a document to assist the communication among those working in the trial. It should also be made available to others upon request. [1] Another document that is really important is the investigator's brochure. In it all the necessary information of the study conduct and study subjects can be found. There is information like dose of the investigational product, safety procedures, frequency of dosing and method of administration of the product.

It can take up to 10 years before an approval is received if the result of all the phases is positive.

The data that is collected in the clinical trials reveals all the differences between the new drugs that are exanimated the clinical trial and the standard of care for treating the targeted disease. A lot of statistical analyses are made with whom will be determined if all the collected information for the new drug is consistent and that everything is done according to the study protocol and the GCP guidelines.

Before permission for the clinical trial is granted an approval from the regulatory bodies of the country in which the clinical trial will be conducted is required. In EU the regulatory bodies are called ethics committees, in USA it is called Institution Review Board. They can perform audits on the sites on which the trials are conducted and at the companies that are arranging and organizing the clinical trials to check if everything is done in the right way, and everything is done according to the GCP Guidelines.

One of the most important parts of the clinical trials is to collect all the safety data, because with this data it can be considered if the new medication or the new procedure is working as it is planned at the beginning of the trial. The collected data at the end is one of the most important parts of the trial that is bringing the result of the trial.

Meta-analysis

Meta-analysis is in general useful when the focus is on an issue for which data is available in several studies, but each individual study is underpowered for that issue. Such issues might be questions related to special subgroups or issues of rare events. Obvious examples of the latter are special, and rare, adverse events. In this respect the respiratory area does not differ much from other areas. The results obtained so far within the respiratory area from meta-analysis are not impressive. [2]

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. The web page is a database of publicly and privately funded clinical studies conducted from all around the world.

The filters that were used to get the results are:

1. Country in which the clinical trials take place, as a country is chosen Republic of North Macedonia,

2. Period in which the clinical trials take place. The start date is chosen to be 01/01/2018, the end date is 01/05/2023.

After getting the results, they are sorted into diagrams for better visual display.

In the results available is information for the number of clinical trials in this period, cities in which the clinical trials are taking places and the type of clinical trials in this period.

Result & discussion

In this study it is presented a statistical analysis of the clinical trials conducted in Republic of North Macedonia in the period of 2018 to 2023.

The major purpose of this study is to get a conclusion if whether and how many clinical trials are conducted in Republic of North Macedonia. To compare the numbers of clinical trials in towns in Republic of North Macedonia, and what kind of clinical tries are taking place in Republic of North Macedonia.

The figures that are shown in this study are publicly available at ClinicalTrials.gov.

According to the statistical information available on ClinicalTrials.gov it can be seen that in Republic of North Macedonia in the period of 2018 to 2023, 42 clinical trials are conducted.

According to the statiscial analysis available on ClinicalTrials.gov it can be seen that all of the clinical trials in Republic of North Macedonia are conducted in Skopje. Of every one of the 42 trials there is a site in Skopje. From the rest of the cities stand out Bitola with 4 clinical trials. Both Stip and Struga have up to 3 clinical trials.

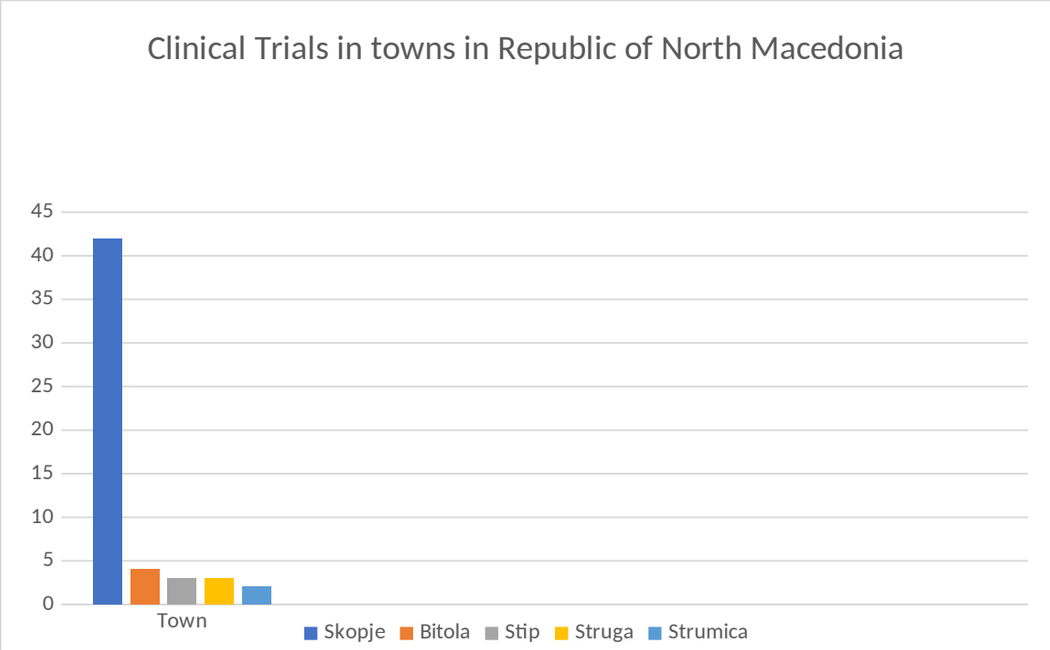

Table [1]

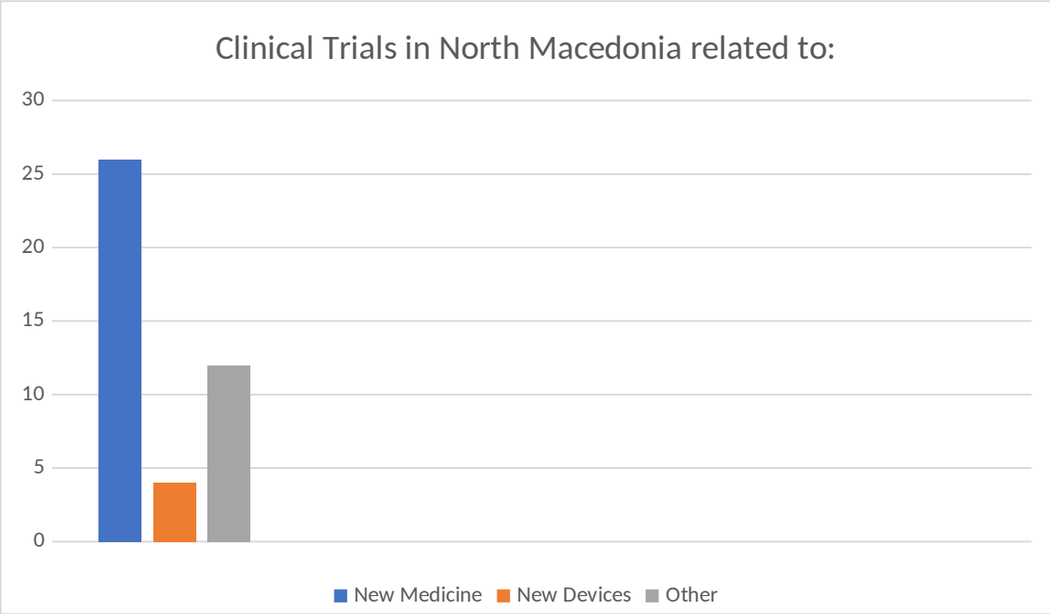

Table [2]

According to the statistical information available on ClinicalTrials.Gov we can see that most of the clinical trials in Republic of North Macedonia are related to new medicines. 26 of the trials are related to new medicines. 4 of the clinical trials are related to new devices. And the rest 12 are related to COVID-19, psychiatric exeminations, epidemiology and ginecology exeminations and questionaires.

Conclusion

The study is based on statistical analysis reported and published on clinicaltrials.gov. From that results and statistical analysis it can be concluded that the number of Clinical Trials in Republic of North Macedonia in the period of 2018 to 2023 is low. In this period there were only 42 trials conducted.

It can be concluded that all the trials are conducted and held in study centers in the Capital city, Skopje. That result is expected because the biggest medical university in Republic of North Macedonia is in Skopje. It is surprising that cities like Bitola, Stip, Ohrid, Kumanovo have a really low number of clinical trials, or there were not clinical trials in these cities.

From the type of the clinical trials conducted in Republic of North Macedonia, most of the clinical trials are related to new medicine. There are only few trials related to new devices, and there are trials related to finding new information in different fields of medicine.

From our experience, Republic of North Macedonia has a big potential for higher number of clinical trials and it can be considered as a serious market for this industry. Some laws need to be updated so the big pharmaceutical and CRO companies can consider North Macedonia as a target country for conducting clinical trials.

References

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[2] 2. Jadad RJ, Moher M, Brownman GP, Booker L, Sigouin C, Fuentes M, Stevens R. Systemic reviews, and meta-analyses on treatment of asthma: critical evaluations. BMJ (2000) 320: 537–40.

Tables:

1. Table 1. Clinical trials in towns in North Macedonia
2. Table 2. Purpose of the Clinical trials in North Macedonia