

# Public awareness and perception of clinical trials in Montenegro

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## SUMMARY

**Introduction:** Clinical trials of medicines are crucial for obtaining relevant information on the efficacy and safety of medicines. Literature data showed that the general public is not sufficiently informed about the purpose and importance of clinical trials. The aim of this study is to investigate awareness of general public in Montenegro regarding clinical trials.

**Methods:** The data from questionnaire completed by 400 randomly selected people aged 18 and over was collected. The questionnaires included questions about CT awareness and perceptions of CT in addition to demographic information.

**Results:** There were statistically significant gender differences with regards to clinical trials awareness. Only 44,2% of all male subjects versus 70,8% of all female ones were informed about the definition of clinical trials ( $p<0,001$ ). While 49,8% women thought that medicines on the market were clinically tested, 47,5% men were not sure about that ( $p=0,037$ ). The main motive for clinical trial enrolment for subjects under the age of 25 and over the age of 50 was curing the existing disease, while for subjects aged 26-50 was eventual financial reimbursement (37,6% and 44,2% versus 34,9%;  $p<0,001$ ).

**Conclusions:** These results indicate that additional educational efforts are needed in order to improve the awareness of significance of clinical trials. Therefore, the Agency for Medicines and Medical Devices of Montenegro will continue its activities in order to promote clinical trials to the general and professional public.

**Keywords:** clinical trial, informing the general population

## INTRODUCTION

According to the Directive 2001/20/EC of the European Parliament and of the Council, clinical trial is any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investiga-

tional medicinal product(s) and/or to study absorption, distribution, metabolism and excretion of one or more investigational medicinal product(s) with the object of ascertaining its (their) safety and/or efficacy [1]. Clinical trials (CTs) are research studies that explore whether a medical strategy, treatment or device is safe and effective for humans [2]. Clinical trials are important from several aspects: to a patient, clinical trial represents a unique

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opportunity to obtain free innovative medicine, i.e. most modern treatment; participants in clinical trials have the opportunity to help with the treatment of certain diseases not to themselves only, but also to future generations. Importance of clinical trials to a researcher is faster access to a new medicine and new treatment options. Clinical trials affect the reputation of researchers, hospitals, universities and society as a whole. Financial aspect is also important, not only in terms of material benefits to researchers and center in which the trial is conducted, but primarily in terms of saving funds necessary for purchasing new medicines that are still being examined or have not yet been placed onto the market [2].

The importance of awareness of the general public about CTs is so that they can decide whether they want to participate in them or not [3]. Positive example of this awareness is that information obtained through clinical trials has helped raise the cure rate for pediatric cancers to more than 70% overall, with some childhood malignancies achieving more than 90% cure rates [4].

This aim of this study was to investigate the awareness of clinical trials, perceptions of favorable feelings about CTs, necessity and safety of them, the ultimate benefit of CTs, as well as the factors associated with willingness to participate in CTs among the general population in Montenegro.

## METHODS

The survey tool consisted of open-ended questions designed by authors that assessed the awareness and attitudes of the individuals regarding the CTs. The data from questionnaire completed by 400 randomly selected people (general population) aged 18 and over was collected. Absolute and relative numbers were used in the description of data. Hi-square test was used to test the hypothesis about the difference of frequency. The statistical hypotheses were tested at the level of statistical significance (alpha level) of 0.05. Statistical data analysis was performed using IBM SPSS Statistics 22.

## RESULTS

The questionnaire was completed by 181 men (45,3%) and 219 women (54,7%) older than 18. Most of the subjects had faculty degree (77,7%), while 7% finished college and 15,3%

finished high school.

The qualitative findings were also borne out in the general public survey with 58,5% (234) of the population claiming to understand the term “clinical trial”, while 75 subjects (18,8%) did not know what CTs are and 91 of them (22,7%) were not entirely certain what the term means. There were statistically significant gender differences with regards to clinical trials awareness: only 44,2% of all male subjects versus 70,8% of all female ones were informed about the definition of clinical trials ( $p < 0,001$ ). Among the subjects who responded that they knew what CTs were, 146 of them (36,5%) obtained the information regarding CTs from media and internet, 57 of them (14,5%) from doctors and pharmacists, while 31 of them (7,8%) got them during their education. When asked – Who has the greatest responsibility for public education about clinical trials – 32,8% of subjects considered it to be Ministry of Health, 28% considered it to be doctors and pharmacists, while 15% considered it to be Agency for Medicines and Medical Devices of Montenegro.

While 49,8% women thought that medicines on the market were clinically tested, 47,5% men were not sure about that ( $p = 0,037$ ). 81,7% of subjects considered that clinical trials had great significance for the development of medicine and treatment of diseases, while 16,3% considered them to be of medium significance. 4 subjects (1%) thought that CTs had little significance and the remaining 4 subjects (1%) considered them entirely unimportant for the development of medicine and treatment of diseases.

33,3% of all participants believed that patients sometimes are involved in CTs without their knowledge, 31,2% thought that it is not so, while 35,5% were not sure.

The main motive to participate in a clinical trial for 37,5% of participants (150) was curing of any illness, for 20,3% (81) it was the possible existence of financial compensation, for 21% (84) it was personal contribution to the development of science and medicine, while for 9,8% (39) it would be the advice by their chosen general practitioner. The remaining 11,5% (46) would by no means want to participate in clinical trials.

The main motive for clinical trial enrolment for subjects under the age of 25 and over the age of 50 was curing the existing disease, while for subjects aged 26-50 was finan-

cial reimbursement (37,6% and 44,2% versus 34,9%;  $p < 0,001$ ).

The main motive for not being involved in the clinical trial for 286 patients (71,5%) was the fear of side effects of a new drug, for 53 (13,3%) it was a lack of trust in doctors, for 33 (8,2%) it was the fear that the drug would not be more effective than current therapy, while for the remaining 28 (7%) it was the time dedicated for frequent check-ups.

Of all participants, 290 said they would never have participated as subjects in clinical trials (72,5%), while 110 (27,5%) would participate in clinical trials. 45,8% participants consider taking part in clinical trials dangerous, 14% consider not dangerous, while 40,2% were not sure.

## DISCUSSION

The results of our study showed that the public awareness of CTs is low. An interesting observation was that in spite of the high education level of our subjects, majority didn't entirely understand the basic concept of CTs. Nearly half of participants believed that medicines which are available to us were not clinically tested, while only a third of participants believed that the patients were not included in clinical trials without their consent.

Very small number of literature references can be found regarding the public awareness of CTs. Results of survey of 1000 healthy adults conducted by Coalition for Clinical Trials Awareness showed that 40% of surveyed adults do not understand clinical trials. Results of survey of 1000 healthy adults conducted by Coalition for Clinical Trials Awareness showed that 40% of surveyed adults did not understand clinical trials [5]. As main reasons for not wanting to participate in a clinical trial approximately half of the respondents gave concerns about treatment effectiveness or side effects (44%), mistrust of research organizations (20%), waiting for treatment approval (18%), and cost (15%) [5]. Meta-analysis of qualitative studies showed that one of the motivating factors to participate in the CTs was the advice from general practitioner. 6 Participants also enrolled in CTs for reimbursement and free treatment [6,7]. Nevertheless, it was noticed that awareness about CTs as a possible treatment option is extremely low, as seen in a study among cancer patients [8]. Several studies showed that creating public awareness

results in positive changes of public attitudes toward CTs and their enrolment, which ultimately leads to various benefits [8,9]. Today, it is obvious that transparency, accountability and accessibility of CTs is crucial in order to re-establish public trust in CTs worldwide [10].

In many countries with developed clinical research practice there are associations for the promotion of clinical trials, with the aim to raise public awareness of the value of clinical research by developing information resources on clinical trials for patients and the public [11,12]. For example, in Great Britain there is UK Clinical Research Collaboration which is promoting active patient and public involvement in clinical research. Work has included creating People In Research, a web resource for patients and the public, and recruiting patient/public members to advisory groups [13]. The Center for Information and Study on Clinical Research Participation (CISCRP) from USA is a nonprofit organization dedicated to educating and informing the public, patients, medical/research communities, the media, and policy makers about clinical research and the role each party plays in the process [12].

The Agency for Medicines and Medical Devices of Montenegro took series of activities to enhance the awareness of professional and general public about clinical trials. Agency for Medicines and Medical Devices issued brochures on clinical trials intended for healthcare professionals and patients, organized two conferences and workshops for all potential participants in clinical trials. However, significant efforts for public awareness through workshops, seminars and mass media like programs on radio, TV, and write-ups in the print media are needed.

Increased awareness can lead to greater participation and consequently greater patient access to new therapies.

## CONCLUSION

The study showed that the public awareness of CTs is low. Although highest ethical and scientific standards relating to procedure of clinical trials approval, conduct and monitoring have been implemented in Montenegrin legislation, results of this investigation indicate that additional educational efforts are needed in order to improve the awareness and understanding

of clinical trials. Therefore, the Agency for Medicines and Medical Devices of Montenegro will continue its activities in order to promote clinical trials to the general and professional public.

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## Stavovi i informisanost opšte javnosti o kliničkim ispitivanjima u Crnoj Gori

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### KRATAK SADRŽAJ

**Uvod:** Klinička ispitivanja ključna su za dobijanje relevantnih informacija o efikasnosti i bezbednosti lekova. Literaturni podaci pokazuju da opšta javnost nije dovoljno informisana o svrsi i značaju kliničkih ispitivanja. Cilj ovog rada je da se istraže stavovi i informisanost opšte javnosti u Crnoj Gori o kliničkim ispitivanjima.

**Metode:** Prikupljeni su podaci iz upitnika koji je popunilo 400 nasumično odabranih odraslih ispitanika. Upitnik se, pored demografskih podataka, sastojao od pitanja koja se tiču stavova i informisanosti o kliničkim ispitivanjima.

**Rezultati:** Ispitanici muškog i ženskog pola se statistički značajno razlikuju u odnosu na informisanost o kliničkim ispitivanjima. Samo 44,2% ispitanika muškog pola u odnosu na 70,8% ispitanika ženskog pola je informisano o definiciji kliničkih ispitivanja ( $p < 0,001$ ). Dok 49,8% žena smatra da su lekovi na tržištu klinički ispitani, 47,5% muškaraca nisu bili sigurni da su lekovi u prometu klinički ispitani ( $p = 0,037$ ). Glavni motiv za kliničko ispitivanje kod ispitanika mlađih od 25 godina i starijih od 50 godina bilo bi lečenje postojeće bolesti, dok bi kod ispitanika uzrasta od 26 do 50 godina glavni motiv bila eventualna finansijska nadoknada (37,6% i 44,2% u odnosu na 34,9%,  $p < 0,001$ ).

**Zaključci:** Dobijeni rezultati pokazuju da su potrebne dodatne edukativne mere kako bi se unapredila svest opšte javnosti o značaju kliničkih ispitivanja. Stoga će Agencija za lijekove i medicinska sredstva Crne Gore nastaviti sa započetim aktivnostima u cilju promocije kliničkih ispitivanja prema opštoj i stručnoj javnosti.

**Ključne reči:** kliničko ispitivanje, informisanost opšte populacije

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