

Assessment of Tunisian acceptance to participate in a Clinical Trial

Evaluation de l'acceptation du tunisien à la participation dans les essais cliniques

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RÉSUMÉ

Les essais cliniques « CT » sont des études de recherche clinique médicale visant à déterminer si différents traitements sont efficaces et sans danger. Certains essais impliquent des patients d'autres des volontaires en bonne santé.

Cette étude vise à évaluer le taux d'acceptation du citoyen tunisien à participer à un essai clinique et à évaluer le niveau de connaissance des essais cliniques. L'étude a concerné 260 participants répartis en trois groupes : personnes en bonne santé (n = 133), médecins (n = 57) et patients (n = 70). L'analyse de nos résultats suggère que, même si la méconnaissance et le manque de volonté peuvent être universellement communs, l'une des lacunes majeures en Tunisie est le manque de communication sur les CT, leurs avantages et la transparence du cadre réglementaire tunisien.

La culture de la recherche et de la formation sur les CT sont absentes aussi.

Dans une interprétation « verre à moitié plein », nos résultats sont encourageants, suggérant que les Tunisiens sont raisonnablement au courant des CT et ils ont une intention positive de participer.

Mots-clés

Essais cliniques - recherche clinique - participation aux essais cliniques - volontaires sains - participants - patients

SUMMARY

«CT» clinical trials are medical research studies to determine whether different treatments are effective and safe.

Some trials involve patients and other trials involve healthy volunteers.

This survey aims to assess CT knowledge and the acceptance to participate to CT of Tunisian citizen.

The study involved 260 participants in three groups: healthy people (n = 133), physicians (n = 57) and patients (n = 70).

The analysis shows that, even if ignorance and lack of will can be universally common, one of the major shortcomings in Tunisia is the lack of communication on CTs, their benefits and the transparency of the Tunisian regulatory framework.

The culture of CT and training on Clinical Research is missing as well.

The results are encouraging, and suggest that Tunisians are reasonably aware of CTs and have a positive intention to participate.

Key-words

Clinical Trials - Clinical Research - participation to clinical trials - Healthy volunteers - participants - patients

INTRODUCTION

Clinical trials "CT" are medical clinical research studies testing whether different treatments are safe and how well they work. Some trials involve healthy volunteers and others involve patients (1).

CT's are the cornerstone of evidence-based medicine. However, they are expensive and time consuming. CT requires the participation, coordination and collaboration of health care providers, patients, administrators, as well as government and private stakeholders (2).

Barriers to participation by any of these groups could be detrimental to efforts to produce the much needed knowledge aiming at progressing healthcare (2). In 2017, a public opinion survey, performed by *Research America*, showed that the percentage of persons refusing to participate to CT because of 'lack of trust in CT' declined by 15% comparing to an equivalent survey performed in 2013 (3). International communication strategies are put in place to encourage patient participation in clinical trials. According to the official clinical trial web site: clinicaltrials.gov, Tunisia conducted 207 CT in many disease areas, with investigators across all the Tunisian territory. This number represents 0,2% of the worldwide CT and only 6% of the MENA region CT (4).

This low level of Tunisian contribution to international CTs may be related to several factors, including lack of awareness or training, willing investigators, appropriate infrastructure across the health care system, or incomplete regulatory framework. This study aimed to assess the acceptance rate of Tunisian citizen to participate in CT and to assess the level of awareness of CT.

METHODS

The study was conducted across all country in public and private healthcare institutions, public places and social networks.

The survey contains eight questions, inquiring about awareness of clinical trials:

- 1/ Existence of international CTs legislation and of the Tunisian regulations,
- 2/ Transparency these regulations,
- 3/ Willingness to participate in a CT, to sign a consent form, to take an investigational treatment, and to randomly take one of the study treatments. The survey had the format of closed questions with three possibilities of answers (yes, no, uncertain opinion). The survey was carried out within

the month of September 2018. The survey questionnaire forms were distributed to participants and collected after one week.

Statistical Analysis: we performed a description analysis, data were culled from questionnaire forms and captured in an Excel sheet. All variables were presented as percentages.

RESULTS

This survey involved 260 participants divided into three groups: Healthy persons (n=133), physicians (n=57), and patients (n=70). Table 1 summarizes survey's data.

The global question "Do you know what a clinical trial is?" showed that more than 60% of the three groups are aware about CT.

Topic 1: Both of physician and patient groups had respectively 40% and 50 % of acceptance to participate to CT.

However, only 20% of healthy persons agreed with CT participation. Among healthy persons and physicians who said they are willing to participate to CTs, more than 70% of them accepted to sign a consent form, however, 23% of patients didn't accept to sign a consent form.

Topic 2: More than 50% of the polled individuals across the three groups said they were uncertain about taking an investigational treatment. Only 25% of physicians agreed to test new investigational treatments in CT. Up to 50% of the three categories of individuals were uncertain about to take randomly one of the study treatments.

Topic 3: The three groups showed a lack of knowledge concerning international regulation and good clinical practice. More than 50% of the three groups were unaware about the existence of a Tunisian legislation. About half of individuals (40% - 69%. across the 3 categories) aware about the existence of CT legislation, were ignorant about the updated legislation in Tunisia.

DISCUSSION

The present survey showed that, overall, Tunisian citizens had a relatively reasonable awareness about CTs, despite the low number of CT conducted in Tunisia compared to other countries in the Region, such as Egypt (4). Also, comparatively, a French survey conducted in 2006, showed a willingness in 69% of 362 patients polled by their general physicians (5). In this survey barriers to participate in a

Table 1 : Survey data

Question	Healthy Person (133)			Physician (57)			Patient (70)	
	Yes	Uncertain	No	Yes	Uncertain	No	Yes	Uncertain
Q-1/Do you know what is a clinical trial?	60 %		40 %	87 %		23 %	64 %	
Q-2/ Are you willing to participate to Clinical Trials	20 %	50 %	30 %	40 %	50 %	10 %	50 %	50 %
Q-3/ Are you willing to sign a trial Consent form	70 %		30 %	88%		12%	23%	
Q-4/ Are you willing to take a new investigational treatment	34%	50%	16%	25%	75%	0%	50%	44%
Q-5/ Are you willing to take randomly one of the trial Treatments	13%	40%	47%	42%	46%	12%	32%	43%
Q-6/ Are you aware of the existence of international Clinical trials legislation	43%		57%	33%		67%	50%	
Q-7/ Are you aware of the existence of the Tunisian CT Regulations	33%		67%	50%		50%	43%	
Q-8/ Are you aware about the transparency of the Tunisian CT Regulation	31%		69%	60%		40%	42%	

CT were multiple and included concerns about safety and effectiveness of the investigational drug, about receiving a placebo, and the whole concept of “experimentation” with its associated perceived ethical issues (5). Another French survey enrolling in 500 persons, performed in 2009, showed that 12% were unwilling to sign a consent form (5).

Our data suggested that, although unawareness and unwillingness may be universally common, one major gap in Tunisia is the lack of communication about CTs, their benefits and the transparency of the Tunisian regulatory framework. Physicians miss the research culture and training. In a ‘glass half full’ interpretation, our results are encouraging, it suggested that Tunisians are reasonably aware about CTs and they have a positive intention to participate. The recent significant upgrade of the Tunisian regulatory framework needs to be better communicated to all stakeholders. It includes the participation of healthy volunteers and other categories of patients with a high level of protection, streamlined and transparent ethical evaluation, and is now at par with the international standards. The most important challenge is to set up an adequate communication plan and instill the culture around innovation and the need for participation to the

global effort of evidence generation, as well as the unmet need of generating knowledge and evidence relevant to the local populations. Providing training in clinical research is essential.

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