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Original Article

Profile of clinical research related to orthopedic disorders in the last five years

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Abstract

Objective: The aim of the study was to identify the profile of clinical research related to orthopedic disorders worldwide.

Methods: A survey of clinical research in orthopedics was performed in the ClinicalTrials.gov platform and Plataforma Brasil databases.

Results: According to data from the ClinicalTrials.gov platform, 1.142 clinical trials related to orthopedic disorders were registered from January 2017 to July 2022. Brazil is in the 14th position in the international ranking, and the Universidade de Sao Paulo (USP) occupies the 6th position among the collaborators who performed the most research in this area. The importance of the foot and ankle area in clinical research related to orthopedic disorders is evident when it is the 7th most studied worldwide and the 2nd most studied in Brazil. Most clinical trials related to orthopedic disorders worldwide target the adult or older adult population and involve interventional studies. On the other hand, most of the clinical trials related to orthopedic disorders in Brazil target the pediatric or geriatric population and involve observational studies.

Conclusion: The profile of clinical research related to orthopedic disorders worldwide showed that most clinical trials targeted the adult or older adult population and aimed to treat patients, not prevent diseases. Brazil targeted the pediatric or geriatric population focusing on characterizing populations and diseases. Clinical research related to orthopedic disorders performed worldwide and in Brazil depended on sponsorship and private institutions.

Level of Evidence IV; Descriptive Observational Study.

Keywords: Clinical trials as topic; Clinical research protocol; Musculoskeletal diseases; Orthopedics; Traumatology.

Introduction

Orthopedic surgery has a long history. While the modern term orthopedics was defined in the early 18th century, orthopedic principles were documented earlier. In ancient Egypt, some orthopedic practices were well documented[1,2]. The Greeks and Romans later began to study medicine more methodologically and improved their understanding of orthopedic anatomy and surgical techniques[3-5]. During the Renaissance, there was a rapid advance in this area of knowledge, such as the description of injuries, surgical technique, and the establishment of orthopedic hospitals; this history provided the foundation for modern orthopedic research[6-8]. In the clinical research and randomized clinical trials era, it is essential to identify the profile of clinical research related to orthopedic disorders conducted worldwide, especially in Brazil, to discuss the challenges involved in this process.

Methods

An observational study including clinical trials exclusively in orthopedics and traumatology. A literature review was performed, considering the following terms: “clinical research and orthopedic disorder.” The search was conducted in the PubMed, Scielo, and Google Academic databases.

Study performed at the Lab. Prof. Manlio Mario Marco Napoli, Departamento de Ortopedia e Traumatologia, Hospital das Clínicas, Faculdade de Medicina, Universidade de São Paulo, São Paulo, SP, Brazil.

Correspondence: Luis Lopez Martinez. Avenida Dr Arnaldo, 455, Pacaembu, 01246-903, São Paulo, SP, Brazil. **E-mail:** luis.martinez@hc.fm.usp.br **Conflicts of interest:** none. **Source of funding:** none. **Date received:** November 13, 2022. **Date accepted:** December 5, 2022. **Online:** December 20, 2022.

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A survey of clinical research in orthopedic disorders was performed in two different databases:

a) **ClinicalTrials.gov platform**: an active search for clinical research related to orthopedic disorders registered on the ClinicalTrials.gov platform was performed; this platform is an international public database maintained by the National Library of Medicine (NLM) at the National Institutes of Health (NIH), in which clinical trials of public or private initiative are registered (https://clinicaltrials.gov/). For this purpose, the ClinicalTrials.gov platform was accessed on July 21, 2022, at 3:00 pm (Brazilian time), and the keywords were used: "orthopedics," "orthopedic disorder," and "Start date from January 2017 to July 2022".

b) **Plataforma Brasil database:** an active search for clinical trials of public or private initiatives related to orthopedic disorders registered on the Plataforma Brasil database was performed. The Plataforma Brasil is a Brazilian, national, public, and unified database of research records involving humans for the entire country. Registration on the Plataforma Brasil database is mandatory for all clinical trials conducted in Brazil. The platform is maintained by the Brazilian government at the National Health Council, an agency linked to the Brazilian Ministry of Health (https://plataformabrasil.saude.gov.br/login.jsf). For this purpose, the Plataforma Brasil database was accessed on July 22, 2022, at 10:00 am, and the keywords were used: "orthopedics," "Start date from January 2017 to July 2022".

Data extracted from the databases were recorded in a spreadsheet using the Microsoft Excel® 2010 program (Microsoft Corporation, Redmond, Washington, USA). After checking the consistency of the data, a descriptive analysis was performed.

Results

According to data from the ClinicalTrials.gov platform, 1.142 clinical trials related to orthopedic disorders were registered from January 2017 to July 2022. During the same period, 350 clinical trials were registered on the Plataforma Brasil database. In addition, according to the data obtained, 228 clinical trials were registered yearly worldwide, whereas, in Brazil, only 70 clinical trials were registered yearly (Figure 1).

Most clinical trials related to orthopedic disorders registered on the ClinicalTrials.gov platform during the period studied were performed in the USA, China, and Canada (Figure 2).

Although the number of clinical trials related to orthopedic disorders registered on the ClinicalTrials.gov platform or Plataforma Brasil database has not shown significant growth since 2018, Brazil is in the 14th position in the international ranking, the same position occupied by Spain and other 20 countries that most performed clinical research related to orthopedic disorders worldwide (Figure 2).

According to data from the Plataforma Brasil database, clinical trials related to orthopedic disorders in Brazil are concentrated in the southeast region and Sao Paulo state (Figure 2). Universidade de Sao Paulo (USP) occupies the 6th position among the sponsors/collaborators who conducted the most research in this area (Figure 3).

According to data from the ClinicalTrials.gov platform and Plataforma Brasil database, the foot and ankle specialty is the 7th most studied worldwide and the 2nd most studied in Brazil among clinical research related to orthopedic disorders

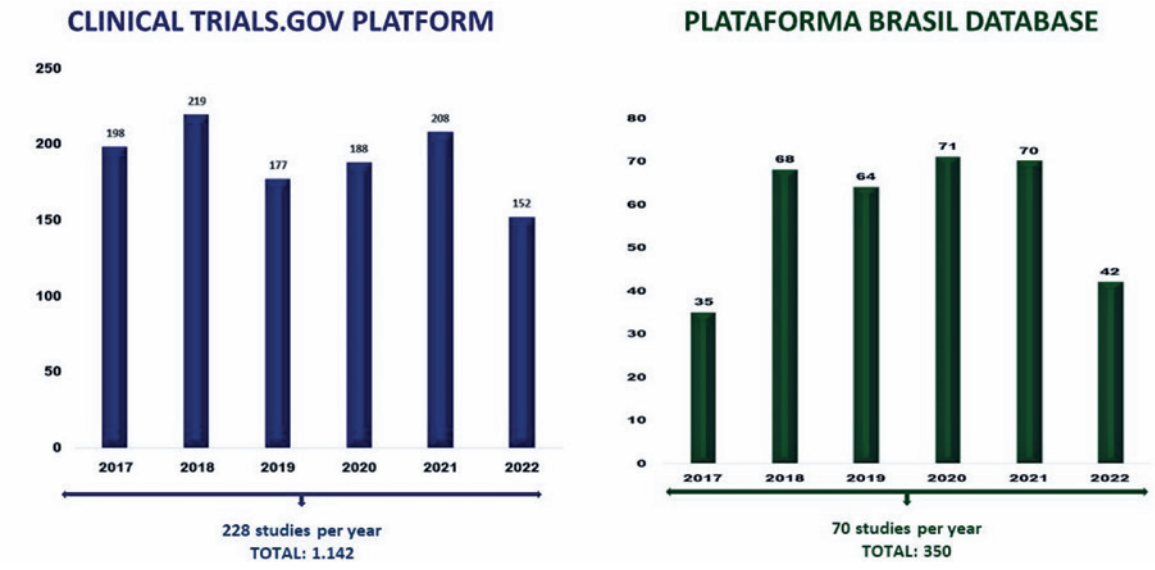

Figure 1. Clinical trials related to orthopedic disorders registered from January 2017 to July 2022. Start Year.

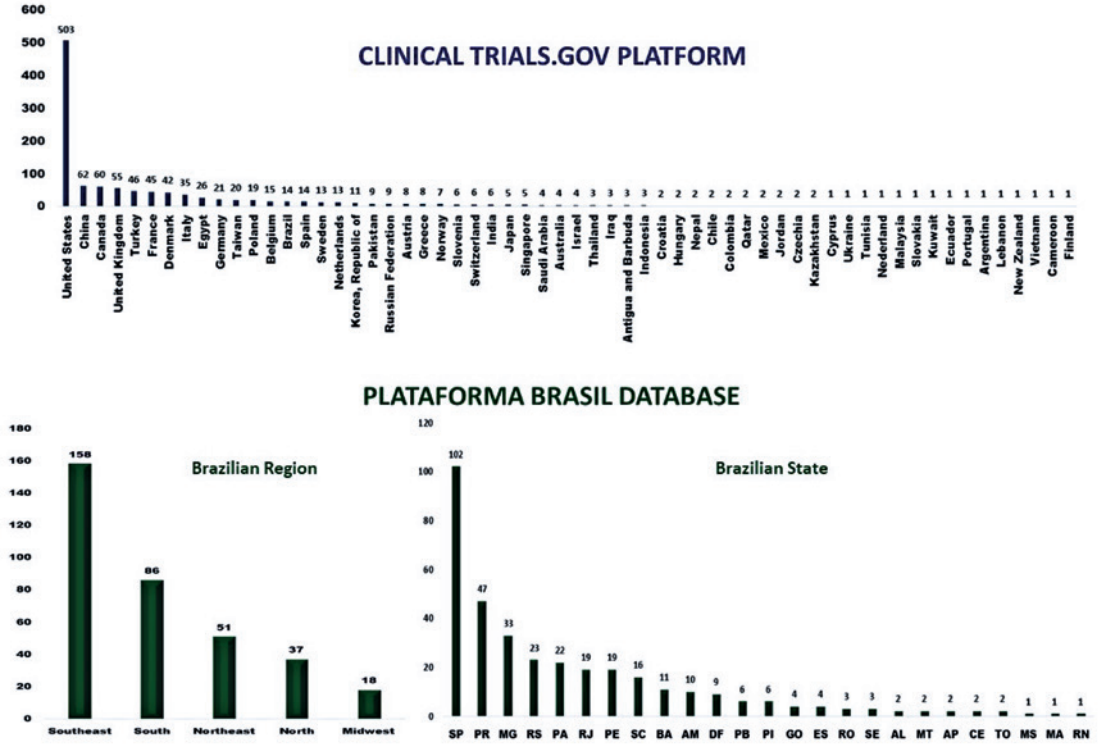

Figure 2. Clinical trials related to orthopedic disorders registered from January 2017 to July 2022. Main Country or State.

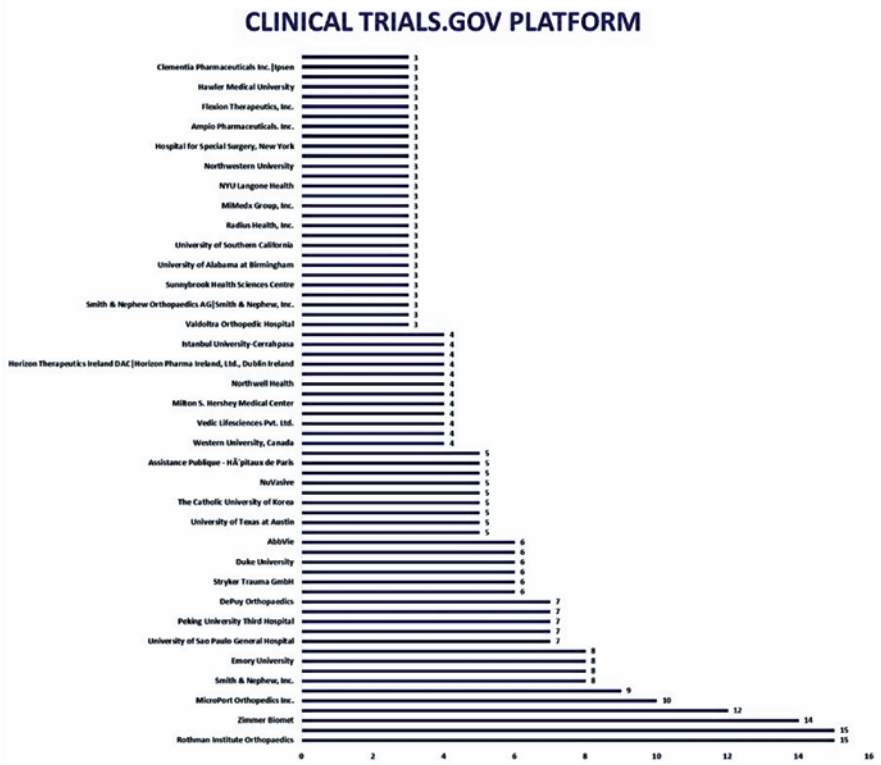

Figure 3. Clinical trials related to orthopedic disorders registered from January 2017 to July 2022. Top 50 sponsors or collaborators.

(Figure 4). Most of these studies target the adult and older adult population, involve devices, drugs, biological products, and were interventionist studies. On the other hand, in Brazil, these clinical trials target the pediatric and geriatric population, involve devices, diagnostic tests or drugs, and were observational studies (Figures 5, 6, and 7). In addition, phase I, II, III, and IV clinical trials were found in this area worldwide, while in Brazil, only phase III and IV (Figure 8).

According to data from the ClinicalTrials.gov platform, most clinical research related to orthopedic disorders received funding from medical industries or the pharmaceutical sector. According to data from the Plataforma Brasil database in Brazil, most clinical research related to orthopedic disorders involves private institutions (Figure 9).

Discussion

When analyzing the number of clinical trials related to orthopedic disorders registered on the ClinicalTrials.gov platform, stagnation was observed in the number of studies in this area since 2018.

As expected, most clinical research related to orthopedic disorders registered on the ClinicalTrials.gov platform from January 2017 to July 2022 was performed in the USA. However, the growth in the number of clinical trials related to orthopedic disorders in China highlights the relevance of this country in the international scenario of clinical research.

Around 70 clinical trials related to orthopedic disorders are performed annually in Brazil. This corresponds to a little more than the mean studies performed in this area yearly worldwide. However, despite a small increase in the number of clinical trials related to orthopedic disorders performed in Brazil between 2017 and 2021, there are few studies in orthopedics and traumatology in Brazil.

However, even without an increase in the number of clinical trials in orthopedics and traumatology in the last five years, Brazil occupies the 14th position in the international ranking alongside 20 countries that most conducted clinical research related to orthopedic disorders worldwide.

According to data from the Plataforma Brasil database, clinical research related to orthopedic disorders in Brazil is concentrated in the southeast and Sao Paulo state.

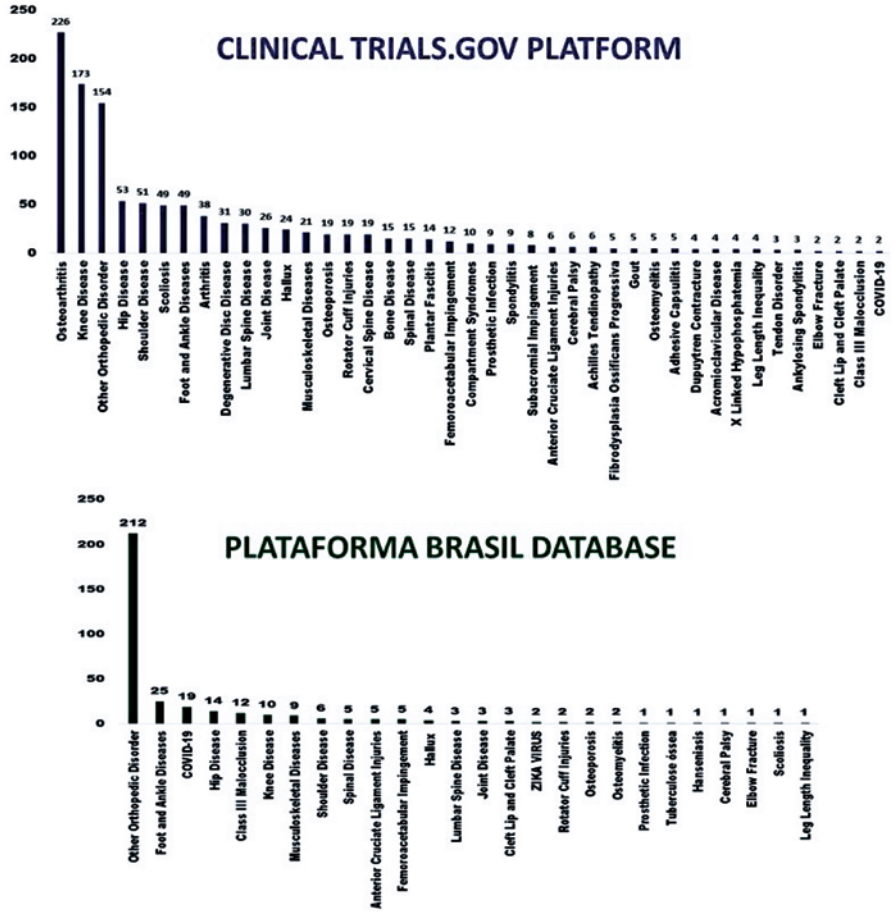

Figure 4. Clinical trials related to orthopedic disorders registered from January 2017 to July 2022. Conditions.

Universidade de Sao Paulo (USP) occupies the 6th position among sponsors/collaborators who conducted the most research in this area. This can be explained because USP is one of the top 150 universities in the world according to the Academic Ranking of World Universities 2022 (ARWU) published by the Chinese consultancy Shanghai Ranking Consultancy[9]. Another reason is the existence of the Fundação de Amparo à Pesquisa do Estado de Sao Paulo

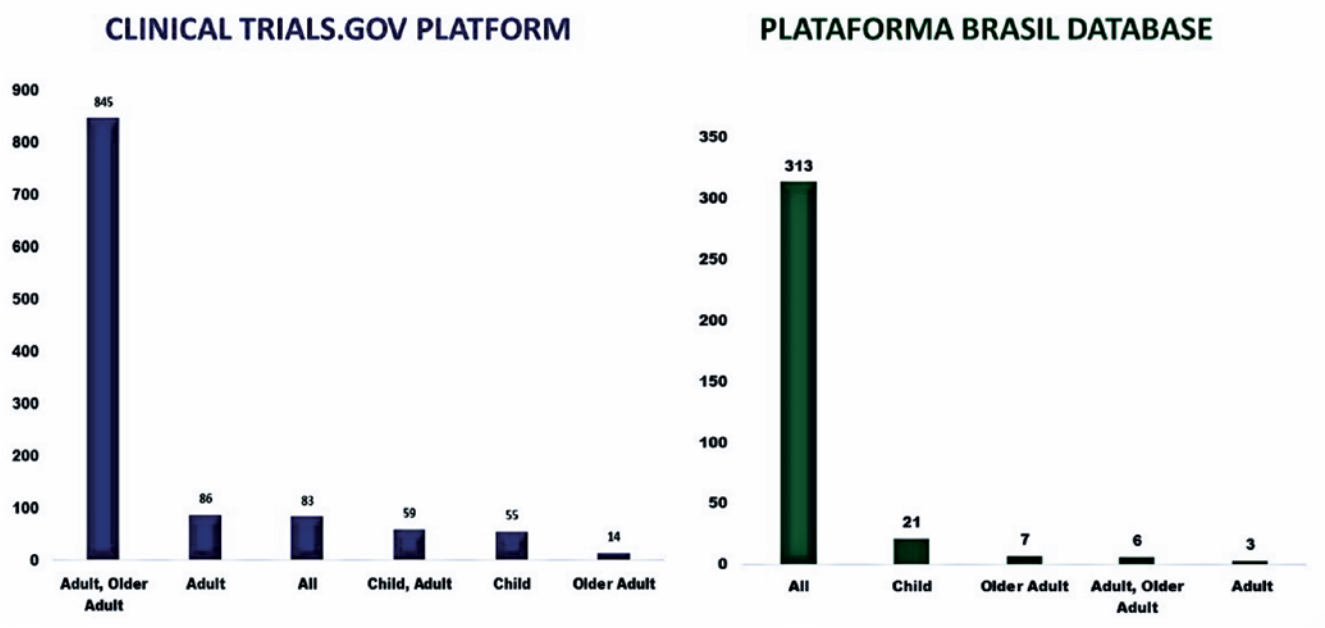

Figure 5. Clinical trials related to orthopedic disorders registered from January 2017 to July 2022. Age.

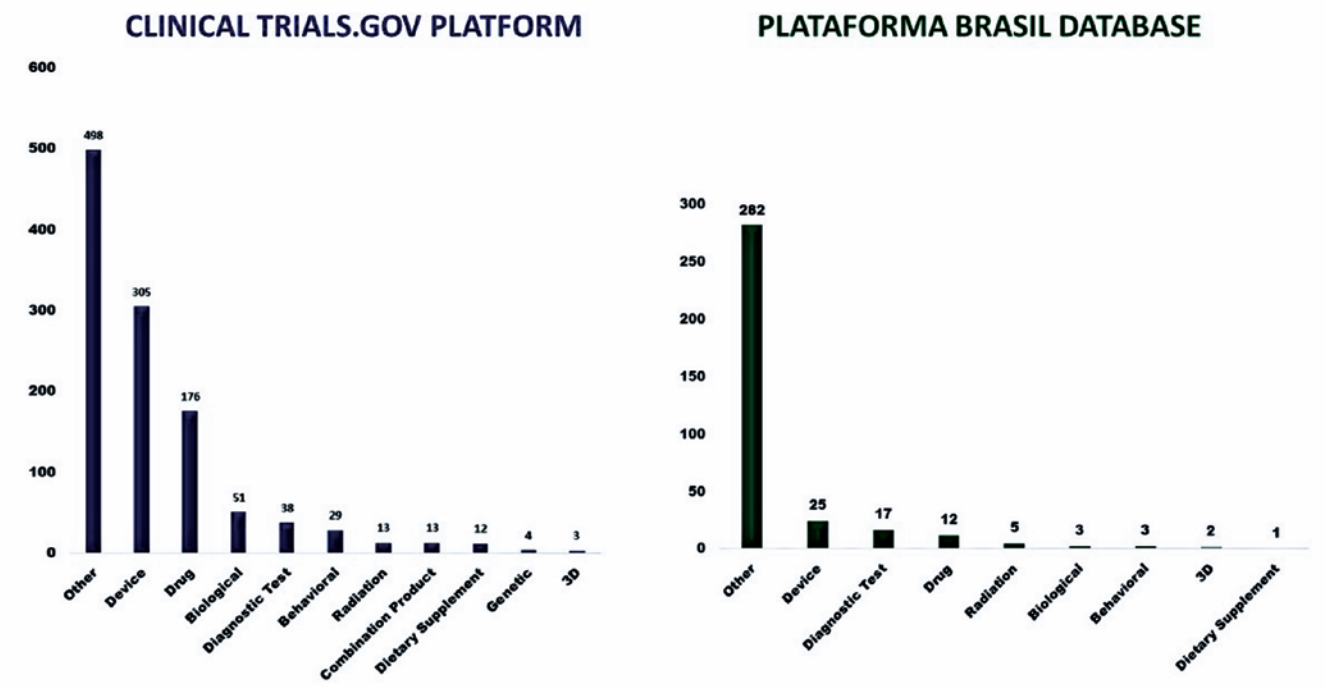

Figure 6. Clinical trials related to orthopedic disorders registered from January 2017 to July 2022. Target.

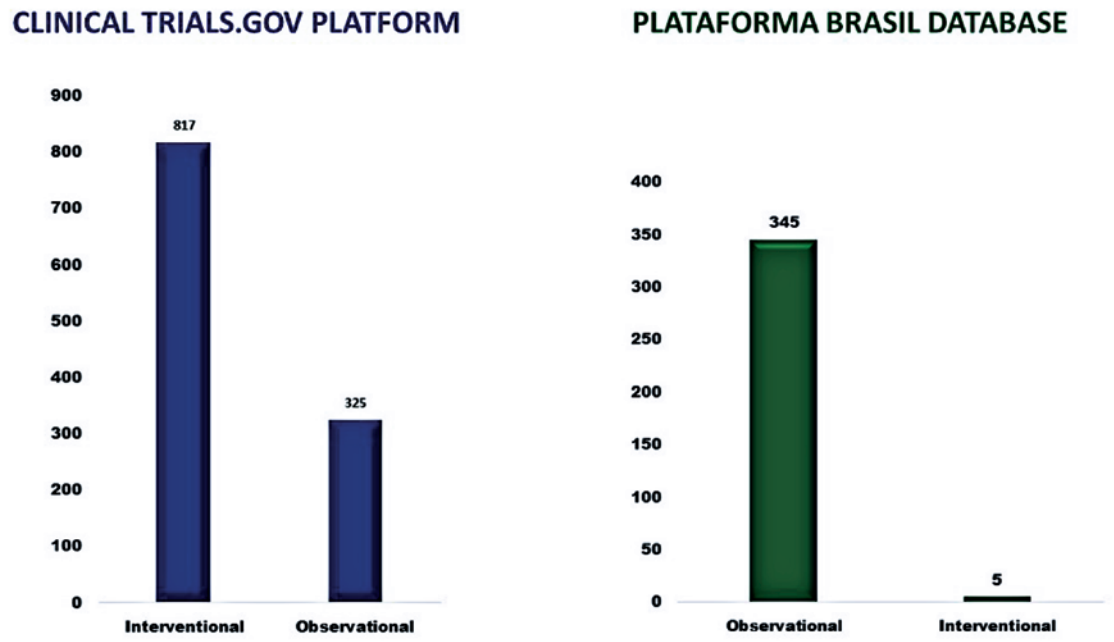

Figure 7. Clinical trials related to orthopedic disorders registered from January 2017 to July 2022. Study type**.**

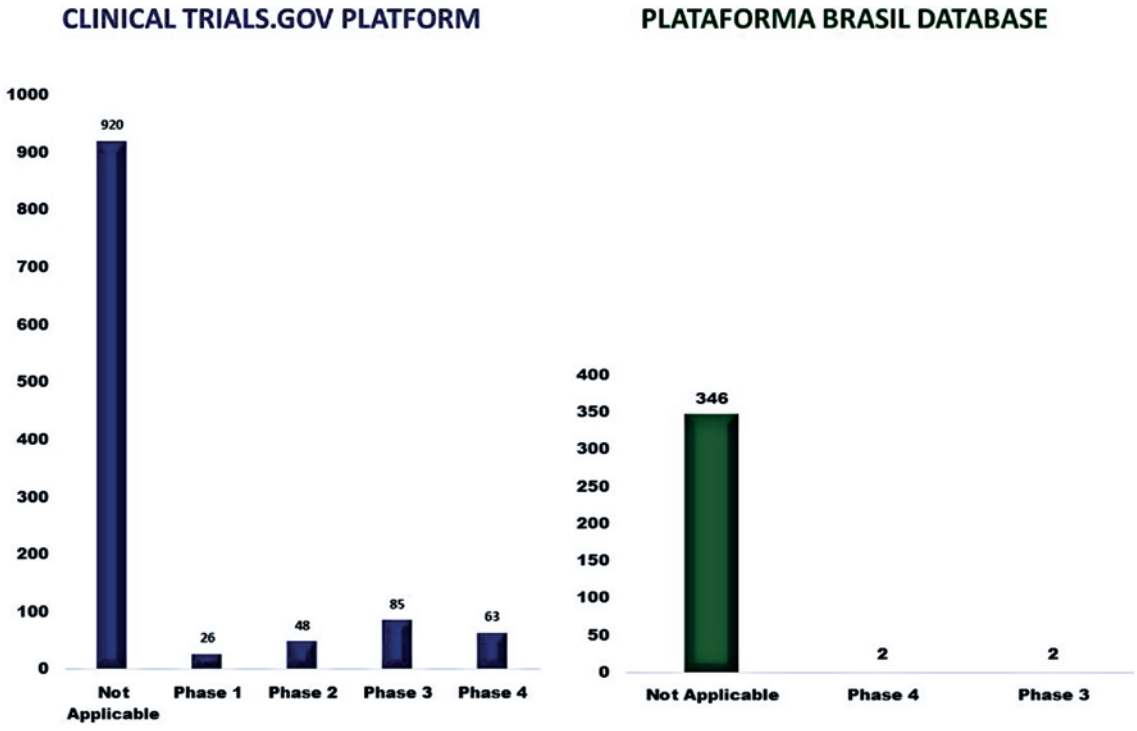

Figure 8. Clinical trials related to orthopedic disorders registered from January 2017 to July 2022. Phase.

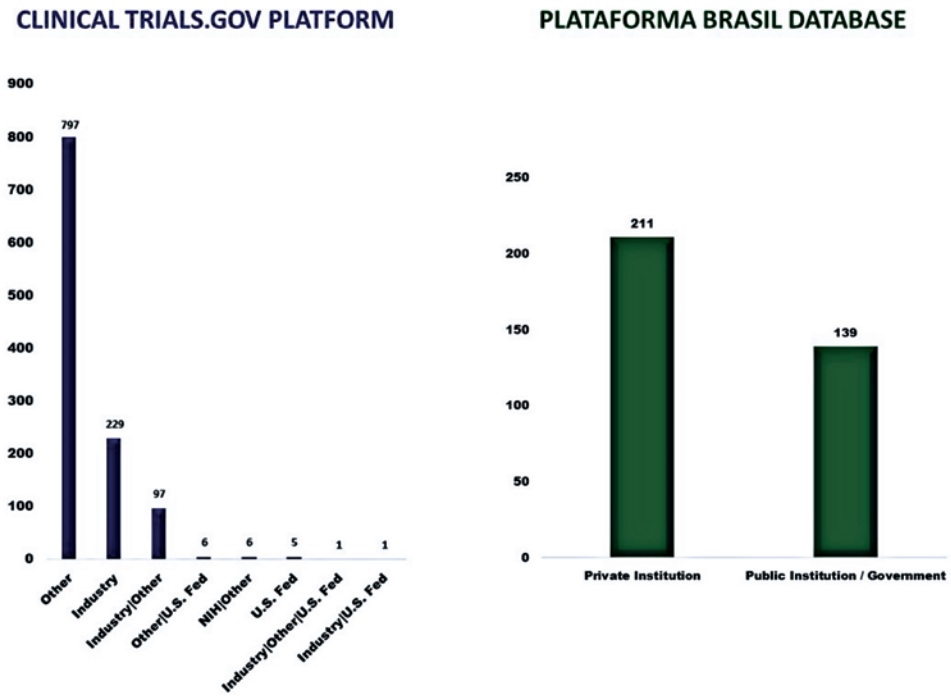

Figure 9. Clinical trials related to orthopedic disorders registered from January 2017 to July 2022. Funded by or institution type.

(FAPESP), one of the main research funding agencies in Brazil. With an annual budget corresponding to 1% of the total tax revenue of Sao Paulo state, FAPESP supports research and finances investigation, exchange, and dissemination of science and technology[10].

According to another international ranking, Quacquarelli Symonds World University Ranking published by the British consultancy Quacquarelli Symonds specializing in higher education, USP is the 115th best university in the world. According to these data, Brazil is the Latin American country with the most institutions ranked in the ranking. In addition to USP, the highest-ranked Brazilian university, four other Brazilian institutions were among the top 500 in the world: Universidade de Campinas (Unicamp - 210th position), Universidade Federal do Rio de Janeiro (UFRJ - 333rd position), Universidade Federal de Sao Paulo (Unifesp - 441st position) and Universidade Estadual Paulista - Júlio de Mesquita Filho (Unesp 477th position). All these universities are located in the southeast region of Brazil[11].

Recently, the Resolution RDC No. 548, of August 30th, 2021, Ministry of Health/Brazilian, National Health Surveillance Agency/Collegiate Board, which provides for clinical trials with medical devices in Brazil, increased requirements to register these products in the country[12]. Therefore, Brazil expects more clinical trials related to orthopedic disorders in the coming years.

The importance of the foot and ankle area in clinical research related to orthopedic disorders is evident when it is the 7th most studied worldwide and the 2nd most studied in Brazil. On the other hand, many clinical trials related to orthopedic disorders registered on the ClinicalTrials.gov platform or Plataforma Brasil database were classified as "Other orthopedic disorder". This reinforces the importance of recording complete and specific information in public databases.

Our results showed that most clinical trials related to orthopedic disorders conducted worldwide targeted the adult or older adult population and involved devices, drugs, biological products, and were interventional studies. This fact, associated with the existence of phase I and II clinical studies, suggests that these clinical trials worldwide are aimed at treating patients.

On the other hand, most clinical trials related to orthopedic disorders performed in Brazil targeted the pediatric or geriatric population and involved devices, diagnostic tests, drugs, and were observational studies. This fact, associated with the predominance of phase III and IV clinical trials and the absence of tests involving biological products, suggests that these clinical trials focus on characterizing populations and diseases.

The results showed, as described in the literature, that there is a worldwide trend in which only when it acquires excellence in phase III studies does a country begin to be considered for more complex studies such as phase I and II.

According to the results, most of the clinical research related to orthopedic disorders performed worldwide and

in Brazil in the last five years depends on sponsorship and private institutions for their realization.

Conclusion

In the last five years, the profile of clinical research related to orthopedic disorders worldwide showed that most clinical trials targeting the adult or older adult population aim to treat patients, not prevent diseases. In Brazil, targets were the pediatric or geriatric population focusing on characterizing populations and diseases. According to our results, most clinical research related to orthopedic disorders conducted worldwide and in Brazil depended on sponsorship and private institutions.

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