

Diverse perspectives from regulatory agencies in Latin America concerning platelet-rich plasma production and use

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The Problem

Despite the increasing use of platelet-rich plasma (PRP) both in clinical practice and in research projects, some uncertainties remain around the standardization of its composition and techniques for its production and application. There is also a need for clinical studies that may testify to its effectiveness and safety. The role of regulatory agencies in this type of scenario needs to be agile, unbiased and based on the best current evidence. Once established and agreed upon, the regulatory requirements should be available to interested parties and stakeholders, including the scientific community, healthcare professionals and decision-makers.

Objectives

To conduct an overall review of regulatory practices concerning platelet-rich plasma use in Latin America.

Methods

Regulatory agencies of Latin America were identified by the search of relevant websites. Electronic searches were conducted employing the term “Plasma rico en Plaquetas” OR “Plasma Rico em Plaquetas” OR PRP, whenever search fields were available. We also searched for additional information on the website. Information concerning the approval of specific devices for PRP production and normative documents were extracted into a previously developed spreadsheet. Searches were last updated on 15 January 2019.

Key Results

We identified 19 regulatory agencies in the following countries: Argentina, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba, El Salvador, Guatemala, Honduras, Jamaica, Mexico, Nicaragua, Panama, Paraguay, Peru, Trinidad and Tobago, Uruguay, and Venezuela. We found no information about the approval of devices specifically developed for PRP production or about directives for the vast majority of the regulatory agencies. Exceptions were the Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT) of Argentina, which has approved devices specifically developed for PRP production, and the Agência Nacional de Vigilância Sanitária (ANVISA) in Brazil. ANVISA stipulated that the clinical indications for PRP use should be determined by the professional councils and that autologous use of PRP obtained from closed systems can be performed in health facilities. A more detailed normative document, addressing the different steps of the production process, are currently being developed.

Conclusions

We summarized the current directives for PRP use in Latin America. Our findings show that this issue is still underappreciated, despite the increasing body of evidence related to the benefits and harms of PRP in distinct clinical scenarios.

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