PD89 Guidance For Designing Pivotal Studies Of High-Risk Medical Devices By International Regulatory Authorities: A Systematic Review

Petra Schnell-Inderst (petra.schnell-inderst@umit-tirol.at), Ursula Rochau, Alan G. Fraser and Uwe Siebert

Introduction: Health technology assessment of medical devices often faces the challenge that approval studies have an insufficient study design. The European Medical Device Regulation (MDR), which has been in force since May 2021, places stricter requirements on clinical studies for high-risk medical devices. One important way of implementing the regulation is through guidance documents from the Medical Device Coordination Group (MDCG).
Methods: Our objective was to systematically identify and analyze recommendations for the design of pivotal studies of high-risk therapeutic medical devices from the MDCG and other regulatory authorities of high-income countries. We systematically searched the websites of regulatory authorities and included both cross-device and device-specific recommendations on clinical trial design for cardiovascular, orthopedic, and diabetes related high-risk medical devices. We extracted and compared the recommendations according to the following seven topics: definitions of study types and level of evidence; need for clinical investigations; appropriate choice of study methodology; general aspects; statistical methods; consideration of context and learning curve; and reporting.
Results: We included 30 documents from regulatory authorities. Eight documents from the European Union (EU) focused mainly on procedural issues and reporting. Guidance on appropriate levels of evidence and choice of study methodology for design and analysis of clinical investigations was missing. Eleven guidance documents were from the United States Food and Drug Administration, which provided detailed recommendations on almost all topics regarding study design as well as new methods. The remaining documents originated from four other countries and the International Medical Device Regulators Forum. A document from Australia included device-specific recommendations but hardly any general recommendations on clinical trials.
Conclusions: The recommendations published to date in the EU are insufficient to support stakeholders in choosing or assessing appropriate study designs to implement the evidence requirements of the European MDR. Detailed guidance from the MDCG is needed to create a common understanding between manufacturers, notified bodies, MDR expert panels, and competent authorities regarding what sufficiency of clinical data means.

PD90 Use Of Medicinal Herbs In Natura By Pregnant Women In The Amazon Region

Celsa da Silva Moura Souza, Erika Barbosa Camargo (erika.barbosacamargo@gmail.com), Rachel Riera, Regismeire Viana Lima, Edson de Oliveira Andrade, Ana Pilar Betrán Betrán and Maria Regina Torloni

Introduction: There are few studies on the use medicinal herbs by pregnant women in Brazil, even though there is a wealth of knowledge about medicinal herbs among Brazilians of Indigenous, African, and European ancestry. The aim of this study was to assess the prevalence and type of herbs used by pregnant women living in the Amazon region.
Methods: This was a cross-sectional study conducted with 811 pregnant women attending 10 public antenatal clinics in Manaus, Amazonas state, Brazil. The consumption of medicinal herbs was assessed through individual 24-hour dietary recall.
Results: A total of 811 women in their second trimester (16 to 20 weeks) of pregnancy were included and 69 (8.5%) reported that they used herbs to make teas. There was a significant difference between users and non-users of medicinal teas, with a higher proportion of overweight women in the group that used teas (46.4% versus 31.9%; p=0.005). Nearly half (47.8%) of those who used medicinal teas consumed herbs with sedative effects, 23 percent consumed herbs for the relief of urinary tract symptoms, and 13 percent used herbs with digestive properties. Most women reported using natural herbs from their own gardens.
Conclusions: Approximately 10 percent of Brazilian women in the Amazon region consumed medicinal herbs to alleviate common symptoms of pregnancy. The most frequently used plants had sedative, urinary tract, or gastrointestinal effects. Most plants were obtained in natura from local gardens. Many of these plants have known adverse effects and their use is contraindicated during pregnancy.

https://doi.org/10.1017/S0266462324003374