Dec 19, 2020

Adverse drug reactions associated with the use of biological agents

PLOS One

Jorge Machado Alba[1], Luis Valladales[2], Yadira Parrado[2]

[1]Universidad Tecnológica de Pereira; [2]Universidad Tecnologica de Pereira

1 Works for me dx.doi.org/10.17504/protocols.io.bkcfkstn

Jorge Machado Alba

ABSTRACT

Introduction: Biotech drugs open new possibilities to treat diseases for which drug therapy is limited, but they may be associated with serious adverse drug reactions (ADRs). The objective was to identify the ADRs associated with the use of biotech drugs in Colombia.

Methods: This was a retrospective study of ADR reports from 2014 to 2019, contained in the database of the pharmacovigilance program of Audifarma SA. The ADRs, groups of associated drugs and affected organs were classified.

Results: A total of 5,415 reports of ADRs associated with biotech drugs were identified in 78 Colombian cities. A total of 76.1% of the cases corresponded to women. The majority were classified as type A (55.0%) and B (28.9%), and 16.7% were serious cases. The respiratory tract was the most commonly affected organ system (16.8%), followed by the skin and adnexa (15.6%). Antineoplastic and immunomodulatory drugs accounted for 70.6% of the reports, and the drugs related to the greatest number of ADRs were adalimumab (12.2%) and etanercept (11.6%).

Conclusions: There has been an incremental increase in the reporting of ADRs associated with the use of biotech drugs in the pharmacovigilance program, related to the strengthening and appropriation of the patient safety culture and improvement in the quality of the generated information. It is important to empower physicians and entire health teams to ensure the traceability of ADRs and to perform interdisciplinary interventions derived from pharmacovigilance at the individual and population levels.

EXTERNAL LINK

https://doi.org/10.1371/journal.pone.0240276

THIS PROTOCOL ACCOMPANIES THE FOLLOWING PUBLICATION

Machado-Alba JE, Jiménez-Morales AL, Moran-Yela YC, Parrado-Fajardo IY, Valladales-Restrepo LF (2020) Adverse drug reactions associated with the use of biological agents. PLoS ONE 15(12): e0240276. doi: 10.1371/journal.pone.0240276

ATTACHMENTS

DB ADR biological Agents.xlsx

DOI

dx.doi.org/10.17504/protocols.io.bkcfkstn

EXTERNAL LINK

https://doi.org/10.1371/journal.pone.0240276

Citation: Jorge Machado Alba, Luis Valladales, Yadira Parrado (12/19/2020). Adverse drug reactions associated with the use of biological agents. https://dx.doi.org/10.17504/protocols.io.bkcfkstn

PROTOCOL CITATION

Jorge Machado Alba, Luis Valladales, Yadira Parrado 2020. Adverse drug reactions associated with the use of biological agents. **protocols.io** https://dx.doi.org/10.17504/protocols.io.bkcfkstn

MANUSCRIPT CITATION please remember to cite the following publication along with this protocol

Machado-Alba JE, Jiménez-Morales AL, Moran-Yela YC, Parrado-Fajardo IY, Valladales-Restrepo LF (2020) Adverse drug reactions associated with the use of biological agents. PLoS ONE 15(12): e0240276. doi: 10.1371/journal.pone.0240276

EXTERNAL LINK

https://doi.org/10.1371/journal.pone.0240276

CREATED

Aug 26, 2020

LAST MODIFIED

Dec 19, 2020

PROTOCOL INTEGER ID

41063

ATTACHMENTS

DB ADR biological Agents.xlsx