

ORAL PRESENTATIONS

[ID-O#108] The characteristics and trends in clinical trials on antidotes registered at ClinicalTrials.gov

Ahmed Fathelrahman^a, Nur Azzalia Kamaruzaman^b, and Sulastri Samsudin^b

*Department of Clinical Pharmacy, College of Pharmacy, Taif University; *Malaysia National Poison Centre, Universiti Sains Malaysia, Penang

Background: ClinicalTrials.gov is a US official website under the National Library of Medicine. It gained researchers' interest as the information source of clinical trials.

Objectives: The objective of the present study was to describe the characteristics and trends in clinical trials on antidotes registered at ClinicalTrials.gov.

Method: On July 11, 2024, we searched the website ClinicalTrials.gov for the intervention "antidote" and the conditions "toxicity", "overdose" and "poisoning". All related studies were downloaded, and further focused on trials with the status "completed". Descriptive analysis was utilized to present the findings.

Results: The search yielded a total of 82 studies, with 43 completed, 12 (recruiting), 6 (terminated), 2 (not yet recruiting) and one (active, not recruiting). Most trials were phase 2 (n=29), followed by phase 1 (n=20), phase 3 (n=16) and phase 4 (n=13). Among completed; the oldest trial "Treatment of Lead-Exposed Children Trial" started on 15/7/1994, completed on 10/6/2015 and produced results last updated on 5/4/2018. The latest trial "Does a Soft Drink Mixture Improve Tolerance of Activated Charcoal in the Adult Poisoned Patient Without Affecting Efficacy" started on 4/1/2023, completed on 14/3/2023, and produced results last updated on 30/5/2024. Forty-two trials included male subjects and 40 included females. By age, 38 studies involved adults (18 − 64 years old), 20 studies involved older adults (65+), and 19 studies involved children (≤17 years). Most studies reported conditions on overdose (n=8), toxicity (n=6), and poisoning (n=6). Examples of other terms used; exposure (e.g. lead exposure), neurotoxicity, snakebites, drug-induced injury, smoke inhalation, nephropathy, death, and acute liver failure. Examples of interventions mentioned; Acetylcysteine (n=8), Naloxone (n=5) Activated Charcoal (n=4), Succimer (n=2), Dimercaptosuccinic acid (n=2), Pralidoxime (n=2), Atropine Sulphate (n=1), Fomepizole (n=1), and Sodium Thiosulfate Pentahydrate (n=1).

Conclusion: ClinicalTrials.gov is a good source of information on trials addressing toxicology-related issues and is recommended for researchers.