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Research Protocol

Animal Research Section

Exploratory Research on the Effectiveness of *Lannea coromandelica* in Streptozotocin Induced Diabetic Model: A Protocol for Systematic Review

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ABSTRACT

Introduction: Diabetes mellitus is a metabolic disorder affecting human population since many centuries ago. To contend this disorder, effective alternative use of non-pharmacological approaches, particularly natural herbal plants, has become a subject of interest since the last decade.

Aim: To evaluate the safety and effectiveness of *Lannea coromandelica* in the management of diabetes mellitus.

Materials and Methods: A systematic review on randomised controlled trials will be carried out. Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines will be followed. The search strategies will be conducted in PubMed/MEDLINE, J-Gate, EMBASE, COCHRANE database and Google Scholar. The search period will be included from 1968 to December 2020. The screening process will be initiated by two authors for title and abstract followed by four authors for full-text articles. The extraction will be performed by using the following characteristics-Study design, Animal model, Intervention of interest.

Conclusion: This current review will provide evidence based on the available literature either to accept or reject the hypothesis that efficacy of *Lannea coromandelica* herbal plant may be beneficial for controlling glucose levels in diabetic model.

Keywords: Diabetes, Herbal plant, Management

INTRODUCTION

Globally, the prevalence of diabetes and its complications has been rising drastically over few decades, particularly in developing countries [1]. This metabolic disorder is being treated with different groups of anti-diabetic drugs effectively, but the medications in long term have side-effects [2]. In modern medicine, alternative use of traditional herbal plants is known to have valuable therapeutic effects in diabetes [3] and significant restorative impact by keeping up better glycaemic control [4]. One such herbal plant is *Lannea coromandelica* [5,6].

Lannea coromandelica, commonly known as Indian ash tree, belongs to family Anacardiaceae and is a tropical deciduous tree. It is abundantly distributed in India, China, Bangladesh, Sri Lanka and Africa [7-13]. Traditionally, bark and leaves of the plant had been used by tribes to cure various diseases. It is also known as Jiga, Wodier, Oti and Mohin [14-17]. The plant is known to possess medicinal properties such as wound healing, anti-inflammatory, anti-microbial, hypotensive, ulcerative stomatitis, gout, cholera, diarrhoea, sore eyes, leprosy, sprains and elephantiasis [8-19].

Various studies have been reported on the anti-diabetic properties of *Lannea coromandelica* extract [1,4,17]. Nevertheless, *Lannea coromandelica* showed promising efficacy over glycaemic control [1,4]. However, one study found no significant hypoglycaemic activity ensured by the plant [17], so it remains unclear whether *Lannea coromandelica* has a role in decreasing blood glucose. Hence, the aim behind conducting this review is to identify and explore the good quality evidence on *Lannea coromandelica* for diabetes mellitus.

MATERIALS AND METHODS

PRISMA guidelines will be adhered to in this review. The PROSPERO registration number is CRD42020169170.

Inclusion criteria: The criteria for the animals to be included in this review will be adult male rat (*Rattus norvegicus*) of Wistar albino strain. Randomised Controlled Trial with standard reference drug (Glibenclamide) will be selected. The preclinical intervention studies that evaluated the safety or efficacy of *Lannea coromandelica* treatment in any timing, frequency and dosage will be included. The authors will search each database from 1968 to December, 2020.

Exclusion criteria: This review will exclude studies done on adult female rat of species other than Wistar albino strain, rats in gestation stage, non-standardised agents for inducing diabetes in animal models, pups and human participants. The studies based on the following outcomes will be excluded urine analysis, biopsy, Globulin and pancreatic enzymes. Books, conference proceedings, conference abstracts, grey literature and languages other than English will not be considered.

Electronic search strategies: Literature will be searched in the following databases-PubMed/MEDLINE, J-Gate, EMBASE, COCHRANE data base and Google Scholar. The keywords will be Herbal plant, Lannea, Streptozotocin, Diabetes, coromandelica, Management.

Selection process: Initially, the screening will be done by two authors independently for title and abstract. The full text articles will be screened independently by two authors to identify studies that meet inclusion criteria. Discrepancies will be solved by a third author.

Data collection process: Data will be summarised in structured tables and figures, characteristics of population, intervention types, content and outcomes. The outcomes will be provided as summary of data, with a graphical representation of each association.

The following data will be extracted from each article-article title, authors, citation, Digital Object Identifier (DOI), type of publication, date of publication, country of origin, sample size, eligibility criteria, name of control drug, intervention parameters (dosage, frequency, duration), start date of enrolment, end date of enrolment, primary outcomes, secondary outcomes, funding information, mode of randomisation, key conclusion, reference to other relevant studies.

Risk of bias in individual studies: No risk of bias will be assessed

Quality assessment: No quality assessment planned

STATISTICAL ANALYSIS

The data will be presented based on homogeneity and heterogeneity. If the studies used same comparator, intervention with outcomes then mean, mean difference and standard deviation will be used for continuous outcomes and Odds Ratio (OD) and Risk Ratio (RR) for dichotomous outcomes. Expected heterogeneity among included studies in which a random- effect model will be the statistical model of analysis by using Rev-Men Review manager. Heterogeneity will be assessed by using Chi-square distribution with (k-1) degree of freedom.

The effect measures for continuous data will be expressed as standardised mean difference, standard deviation with 95% confidence interval and for dichotomous data, measures of treatment effect will be OD and RR.

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