Investigator Brochure for TecMind01 Protocol

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Title Page:

- Investigator Brochure for the TecMind01 Protocol
- Title: Evaluation of the correlation between diet quality, weight status and mental health in children, with emphasis on the identification of plasma and urinary biomarkers.
- Investigational Product: Nutritional Study in Children
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1. **Introduction**: Welcome to the Investigator Brochure for the TecMind01 Protocol. This document provides essential information for investigators involved in the study focused on evaluating the correlation between diet quality, weight status, and mental health in children, with emphasis on identifying plasma and urinary biomarkers.
2. **Investigational Product Overview**: This study does not involve the use of investigational drugs. Instead, it focuses on assessing the nutritional status of pediatric participants aged 5 to 11 years. The investigational product in this context refers to the dietary intake of participants and the potential biomarkers associated with diet quality.
3. **Study Design and Methodology**: The study design is experimental, descriptive, and prospective, with the aim of investigating the correlation between diet quality, mental health status, and weight status in Mexican children. Participants will undergo anthropometric evaluation, mental health assessment, dietary intake reporting, and blood/urine sample collection for biomarker analysis. The study consists of 2 parts, the first being a nutritional diagnosis of all the players of the Mexican Football League (MFL) where the weights and sizes, gender and age of all the members will be retrospectively reviewed to carry out a nutritional evaluation based on the Body Mass Index (BMI), at the same time the self-completion diet quality survey will be sent via email to be completed by parents. Once the first phase is finished, the patients who will enter the second phase of the protocol will be selected under the following guidelines:

Group 1: Obesity

Inclusion criteria:

Pediatric patients from 5 to 11 years old.

BMI greater than or equal to the 95th percentile for your age and sex, according to the standards of the World Health Organization (WHO) or the Centers for Disease Control and Prevention (CDC).

Exclusion criteria:

Medical conditions that may affect metabolism or body composition.

Use of medications that can influence metabolic biomarkers.

Group 2: Without Obesity

Inclusion criteria:

Pediatric patients from 5 to 11 years old.

BMI between the 5th percentile and the 94th percentile for your age and sex, according to WHO or CDC standards.

Exclusion criteria:

Obesity or BMI above the 94th percentile.

Medical conditions that may affect metabolism or body composition.

Suspension Criteria:

1. Patients who do not complete the surveys in the established time and manner.
2. Patients who do not undergo laboratory studies on the dates or places indicated.

Participants will undergo anthropometric assessment, mental health assessment, dietary intake reporting, and blood/urine sample collection for biomarker analysis in a single visit.

4. **Biomarkers and Sample Collection**: The blood and urine samples will be taken at the External Laboratory of Hospital Zambrano Hellion. The blood sample will be processed for complete blood count, HOMA index, 4 to 24-element blood chemistry, lipid profile, and thyroid profile studies. The urine sample will be processed for a general urine examination. A reserve of plasma and urine samples will be used for both targeted and untargeted metabolomics studies.
5. **Safety Information**: As this study involves minimal risk to participants, safety considerations primarily focus on ensuring the ethical conduct of research and the protection of participants' rights and well-being. Adverse event reporting procedures will be implemented as per regulatory requirements.
6. **Investigators' Responsibilities**: Investigators conducting the study are responsible for adhering to the study protocol, ensuring participant safety and welfare, accurately collecting and documenting data, and complying with regulatory requirements and ethical standards.

Appendices:

- Study-specific forms
    - Consent form
    - Assent Form
    - Excel Data collection sheets

- Glossary of terms

  BMI= Body Mass Index
  CDC= Centers for Disease Control and Prevention
  MFL= Mexican Football League
  WHO= World Health Organization

- References

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Revision History:

- April 2024 : Version 1.0 - Initial Compilation
- [Date]: Version 1.1 - [Description of Revisions]
- [Date]: Version 2.0 - [Description of Revisions]