ESTIMATION OF TOTAL IRON AND TRANSFERRIN BOUND IRON (TBI) IN HUMAN SERUM USING ICP-OES AND ITS APPLICATION ON BIOEQUIVALENCE STUDIES OF IRON-SUCROSE INJECTION

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INTRODUCTION

A million people are affected by iron-deficiency anaemia worldwide [1]. Iron therapy, commonly administered as iron dextran, is in addition to managing anaemia provides a potentially rich opportunity to study iron absorption in real-time. Understanding the pharmacokinetics of iron in human serum is essential to appraise various iron injection products in comparison and also to patients’ needs to do iron supplementation. After preclinical pharmacokinetics, the composition of iron was found to be incompletely understood. Most relevant analysis of the iron distribution has been typically measured by the transferrin saturation, which can be indirectly measured through tissue iron. Development of these pharmaceutical agents requires pharmacokinetic studies on healthy and iron-supplemented subjects to achieve good outcomes. Several quantitative descriptors of serum iron components to determine iron pharmacokinetics were necessary. Several studies present non-serum studies to indicate conventional methods for TBI analysis that either, underestimate or overestimate, due to the complex nature of iron absorption and 2 metallic iron solutions. High-resolution MRS of TBI is a non-invasive technique to examine the plasma iron content, it helps in understanding the clinical outcomes of iron therapy. In this study, we aimed to evaluate the bioequivalence of iron injection products.

MATERIALS

The volunteers were of 35-55 years old and had no allergies to iron. All volunteers were included following a standardised diet and no iron therapy had been received in the previous 6 months.

The accuracy of the method was assessed using a normal saline solution with iron and transferrin treated with Enteral Iron Treatment. No significant differences were observed between the treated and untreated sample.

METHOD VALIDATION

The placebo analysis was performed on 10 volunteers, as per the protocol of ICP-OES. No significant differences were observed between the placebo and treated samples.

The accuracy of the method was assessed using a normal saline solution with iron and transferrin treated with Enteral Iron Treatment. No significant differences were observed between the treated and untreated sample.

RESULTS

The results were compared with the results of a colourimetric method and calculated by P.S.F. The results were in line with the literature.

NOVEL ASPECTS

The study also includes a colourimetric method with a calibration curve of iron. The results of five different iron preparations were compared with the literature.

REFERENCES


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This Poster is presented at 11th Workshop on Recent Issues in Bioanalysis, Los Angeles, University of California.