

## SECTION I

### GENERAL CONSIDERATIONS

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## CHAPTER 1

### OBJECTIVES OF THE PRESENT STUDY

1. TO ESTABLISH A PRACTICABLE METHOD FOR SERUM IRON ESTIMATION.

Serum iron estimation is an important and interesting but at the same time very laborious and time-consuming procedure. It is therefore essential to establish a practicable method which is simple, sensitive, rapid, reliable, easily operable, producing consistent results and relatively economical.

2. TO STUDY THE STABILITY OF THE COLOUR FOR SPECTROPHOTOMETRIC READING IN SERUM IRON ESTIMATION.

It has been claimed that the colour for the Spectrophotometric reading in serum iron estimation is not stable

and hence the readings should be taken within half hour of the development of the colour. This is not easy enough and may not be possible at the time of each estimation because of various reasons, e.g. sudden stoppage of electric supply or the spectrophotometer which is a very delicate instrument might suddenly <sup>go</sup> out of order for some unknown reason. Under the circumstances, if the stability of the colour is established, it can prove itself of utmost importance, and of great aid and relief to the investigators, as the readings can be taken at a later convenient time. Therefore, the investigator may not need the repeatation of the whole procedure of serum iron estimation whenever he fails to take the readings within half an hour of the development of the colour.

3. TO DETERMINE THE SERUM IRON VALUES IN NORMAL SUBJECTS (NORMAL ADULT MALES AND NORMAL ADULT FEMALES) WITH THE METHOD ADOPTED IN THIS STUDY AND IN THE TYPE OF SUBJECTS SELECTED FOR THE STUDY.

It is highly necessary that each investigator must have his own standards. Evidently, it becomes clear that the determination of serum iron values in normal subjects (Normal Adult males and Normal Adult Females) with the method adopted in this study as also in the type of subjects selected for the study is highly essential. This in turn facilitates the accurate comparison of the serum iron values in normal subjects and

in Anaemic subjects.

4. TO DETERMINE THE SERUM IRON VALUES IN ANAEMIC SUBJECTS (MALE ADULT PATIENTS AND FEMALE ADULT PATIENTS OF IRON DEFICIENCY ANAEMIA).

This determination, besides the routine investigations will enable to establish the diagnostic importance of serum iron estimation in iron deficiency anaemia cases.

5. TO TAKE COMPARATIVE CLINICAL TRIALS OF FERROUS SULPHATE AND FERROUS FUMARATE IN IRON DEFICIENCY ANAEMIA CASES UNDER STANDARD CONDITIONS.

Ferrous Sulphate is the well-known, popular and time-honoured drug whereas Ferrous Fumarate is a new drug in the market. Naturally, it becomes important and necessary to determine and compare the therapeutic efficacy of these two iron preparations by taking their comparative clinical trial in iron deficiency anaemia cases. This eventually will help in selecting the better preparation, out of the two, for oral therapy of iron deficiency anaemia.

6. TO STUDY THE DIFFERENCE IN ABSORPTION OF FERROUS SULPHATE AND FERROUS FUMARATE BY COMPARING THE SERUM IRON RESPONSE AFTER ADMINISTRATION OF FERROUS SULPHATE OR FERROUS FUMARATE IN IRON DEFICIENCY ANAEMIA CASES UNDER STANDARD CONDITIONS.

One of the methods for studying the iron absorption is the determination of serum iron response to a test dose of iron preparation under consideration. Thus, the absorption of two iron preparations can be studied by comparing serum iron responses after administration of ferrous sulphate and ferrous fumarate in cases of iron deficiency anaemia under standard conditions.

7. TO STUDY THE DIFFERENCE IN SERUM IRON RESPONSE AFTER ADMINISTRATION OF FERROUS SULPHATE IN IRON DEFICIENCY ANAEMIA CASES ON FIRST AND LAST DAY OF TREATMENT UNDER STANDARD CONDITIONS.

This study will enable to determine and compare the difference, if any, in the absorption of Ferrous Sulphate in severally anaemic patients and in the same patients three weeks after the iron therapy with Ferrous sulphate.

8. TO STUDY THE DIFFERENCE IN SERUM IRON RESPONSE AFTER ADMINISTRATION OF FERROUS FUMARATE IN

IRON DEFICIENCY ANAEMIA CASES ON FIRST AND  
LAST DAY OF TREATMENT, UNDER STANDARD CONDITIONS.

This study will enable to determine and compare the difference, if any, in the absorption of ferrous fumarate, a new drug in the market, in severally anaemic patients and in the same patients after three weeks of iron therapy with ferrous fumarate.

9. TO STUDY THE SEX-WISE DIFFERENCE, if any, IN  
SERUM IRON RESPONSE TO IRON THERAPY IN IRON  
DEFICIENCY ANAEMIA CASES.

Comparison of serum iron response to iron therapy in male and female patients of iron deficiency anaemia will enable to find out whether or not the factor of sex has got any appreciable difference in response to iron therapy.

10. TO ESTABLISH A PRACTICABLE METHOD FOR THE  
ESTIMATION OF ELEMENTAL IRON CONTENT IN A  
TABLET OF IRON PREPARATION.

In a clinical trial of any iron preparation, or in a comparative clinical trial of two or more iron preparations, it is of utmost importance to adjust the doses EQUAL in terms of Elemental Iron in mg. per day. Thus, estimation of elemental iron per tablet of the particular iron preparation will enable to confirm that the

theoretically calculated dosage of the iron preparation is in accordance with what the patient is actually getting in reality.

11. TO STUDY THE ELECTROCARDIOGRAPHIC CHANGES IN IRON DEFICIENCY ANAEMIA.

It has been shown that electrocardiogram does show important changes in some of the severe cases of iron deficiency anamia. Therefore, such type of study is interesting in establishing the frequency of such changes and also in determining its importance in avoiding the wrong diagnosis of a condition, whose Electrocardiographic pattern might mimic those found in iron deficiency anaemia.

12. TO STUDY THE AETIOLOGY AND TYPE OF ANAEMIA IN HOSPITAL CLASS OF PATIENTS.

The study of the aetiological factors of iron deficiency anaemia in order of occurrence and hence in order of importance, can help in preventing the disease. The study of the type of anaemia is also important from the therapeutic point of view.