EFFICACY & TOLERABILITY OF BETA INTERFERON IN A COHORT OF INDIA PATIENT AT A QUATERNARY CARE HOSPITAL: A PILOT STUDY

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ABSTRACT

This study focuses on Beta Interferon mechanisms of action, evidence of efficacy, safety, and tolerability in a cohort of Indian patient at a quaternary care hospital: A Pilot Study. I have given a brief idea about the multiple sclerosis as Beta Interferon had shown effective decrease in relapse of multiple sclerosis. We will enroll those patient in our study to whom Beta Interferon will be prescribe by the physician. In this synopsis I had did extensive literature review of previous research performed related to Beta Interferon. I have reviewed that Beta Interferon have been extensively used for Multiple Sclerosis, Rheumatoid Arthritis or any autoimmune related diseases. In Japan a study had shown safety profile in cancer patient treating with Beta Interferon.

I. INTRODUCTION

1.1 Beta Interferon

GENERIC NAME	BRAND NAME
Beta Interferon	Avonex, Betaseron, Extavia and Rabif

1.1.2 Mechansim of Action

IFN β was first tested for treatment of MS due to its antiviral property, as it was thought that the cause of the disease lay in a viral infection. Today, although viral infections are still considered and studied, at least as contributory factors, IFN β is regarded more as an immunomodulatory and antiproliferative treatment. Laboratory and clinical studies have in fact shown that it inhibits MS activity, acting on a variety of processes and molecular mediators within the immune system. IFN β modifies the cytokine production in favor of the antinflammatory subset, such as Il-10 and Il-4, inhibiting the release of proinflammatory cytokines such as IFN β and tumor necrosis factor (Rothuizen et al 1999; Yong et al 1998). Other pharmacodinamic properties of IFN β include inhibition of T-cell activation, block of production of oxygen free radicals by mononuclear phagocytes, and reduced expression of major histocompatibility complex class II molecules, which in turn reduces self-antigen presentation in the CNS (Dhib-Jalbut 2002). A recent ex vivo and in vitro longitudinal study demonstrated that IFN β in its 1a form enhances CD4+ regulatory T cells activity (de Andres et al 2007). Beneficial effects of IFN β may also be due to to a protective role exerted at the level of the blood-brain barrier (BBB), by reducing the activity of metalloproteases that are responsible for BBB disruption, and/or by preventing adhesion and subsequent migration of T-cells into the CNS (Galboiz et al 2001). In particular, it was

demonstrated that IFN β 1a regulates the expression of serum and membrane-associated intercellular adhesion molecules (Giorelli et al 2002), and it is associated with up-regulation of vinculin and N-cadherin expression in brain endothelial cells (Harzheim et al 2004) restoring BBB disruption IFN β action-related.

Most of these pharmacodynamic properties depend on the interaction of IFN β with cell surface receptors (Wagstaff and Goa 1998). This interaction induces an intracellular signal cascade leading to the expression of IFN-stimulated genes, whose products such as neopterin, myxovirus resistance protein A, β 2 microglobulin, and 2',5'-oligoadenylate synthetase, besides carrying out the effect of IFN, have also been studied and proposed as a tool to monitor the drug activity, and potentially the biological response to treatment (Bertolotto et al 2001).

However controversial the definition of IFNs β as disease-modifying drugs may be, recent experimental studies have proposed a novel and neuroprotective mechanism of action for IFN β. The survival of retinal ganglion cells in the animal model MS, the experimental autoimmune encephalomyelitis, was enhanced by treatment with IFN β 1a (Sättler et al 2006). In addition, another study proved that IFN β stimulates the secretion of nerve growth factors by endothelial cells (Biernacki et al 2005). This axon protective effect was related to the antinflammatory properties of the drug.

1.2 Background Study

1.2.1 Over the last 15 years, pivotal randomized, multicenter, double-blind, placebo-controlled studies have led to the market licence of interferons beta (IFNs β) for the treatment of RR MS (The IFNB Multiple Sclerosis Study Group 1993; Jacobs et al 1996; PRISMS Study Group 1998) and to its worldwide use in clinical settings.

1.2.2 Additional studies have then assessed efficacy of IFNs β in clinically isolated syndromes (CIS) likely to develop MS (Jacobs et al 2001; Comi et al 2001), and in SP forms of the disease with superimposing relapses (European Study Group on Interferon beta-1b in Secondary Progressive MS 1998;Secondary *P*rogressive *E*fficacy *C*linical *T*rial of *R*ecombinant *I*nterferon-beta-1a in *MS*(SPECTRIMS) Study Group 2001

II. AIM AND OBJECTIVE OF STUDY

2.1AIM

"Efficacy & Tolerability of Beta Interferon in a cohort of Indian patient at a quaternary care hospital: A Pilot Study"

2.2 Plan of work

- A detailed literature review had been performed regarding efficacy and tolerability of Beta Interferon in various tertiary & quaternary care hospitals.
- On the basis of literature review we have decided to study the efficacy and tolerability of Beta Interferon in various quaternary & tertiary care hospital.
- The study will be conducted after approval from the Institutional ethic committee and Institutional Scientific Committee
- Informed consent form for participation will be collected from patient prior to data collection.
- A drug monitoring Performa will be use to collect study specific data after approval.
- The data will be collected using various data sources and analysis will be made on efficacy and tolerability of Beta Interferon.

- Patients will be selected on the basis of inclusion and exclusion criteria.
- Sample size of patient 20 + 2 treating with Beta interferon will be included.

2.3 Study Criteria

2.3.1 Inclusion Criteria

All patients treating with Beta Interferon (In-patients as well as out patients) with co-morbidity in Fortis Memorial Research Institute, Gurgaon, Haryana**.**

2.3.2 Exclusion Criteria

- Critically ill patients in ICU or Critical care setting
- History or presence of malignancy.

2.4 Duration of Study

October 2014 to January 2015

2.5 Sample Size

20+2

2.6 Data Elements

The following details will be entered:

- Demographic profile of the patient will be noted.
- The diagnosis will be noted.
- Prescribed beta interferon drug and its dose/frequency/duration will be noted.
- Any co-morbid condition will be noted.

2.7 Source of Data

- Patient's Medical Records.

III. RESULT & DISCUSSION

We will report here the study titled **"Efficacy & Tolerability of Beta Interferon in a cohort of Indian patient in a quaternary care hospital: A Pilot Study".**

This is a Pilot study which will be carrying out from October 2014 in IPD and OPD of Fortis Memorial Research Institute, Sector-44 Opposite Huda city Metro Station, Gurgaon, Haryana (India).

The study of efficacy and tolerability of Beta Interferon is component of clinical research which will seeks monitoring & evaluation as it is necessary to identify safety assessment and adverse event occur in Indian patient treating with Beta Interferon.

3.1 Result

In Results we will monitor these aspects

3.1.1 Demographic Profile of the Study Population

a. Age
b. Gender
c. Stage of multiple sclerosis among patients
d. Co-morbidities

3.1.2 Diagnostic Parameter

3.2 Discussion

This study will evaluate and discuss the efficacy and tolerability of beta interferon in a cohort Indian patient at a quaternary care hospital: A Pilot study.

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