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Clinical Study Report

Protocol No: BNL- 002

An Interventional / Prospective Phase II Accelerated Study To Determine The Efficacy & Safety Of RECEPTOL® Liquid Spray Used As A Stand-Alone Mono Therapy in HIV / AIDS Patients with multiple symptoms

1. TITLE PAGE

STUDY TITLE	An Interventional / Prospective Phase II Accelerated Study To Determine The Efficacy & Safety Of RECEPTOL® Oral Spray Used as A Stand-Alone Mono Therapy in HIV / AIDS Patients with multiple symptoms
PROTOCOL CODE	BNL-002
NAME OF INVESTIGATIONAL PRODUCT TESTED	RECEPTOL® Oral Spray
DEVELOPMENT PHASE OF STUDY	Phase II
INDICATION STUDIED	HIV/AIDS
TRIAL DESIGN	Interventional / Prospective, 90 days study in 30 subjects to determine effect of treatment with RECEPTOL® on HIV Viral Load HIV / AIDS related clinical symptoms
STUDY INITIATION DATE	March, 2000
STUDY COMPLETION DATE	August, 2000
SPONSOR	Biomix Network Limited A2101 -04, Mansarovar, Neelkanth heights , Pokhran Rd 1 , Thane West 400606, India What's all contact : +91 82910 84108
PARTICIPATING INSTITUTES	**PRINCIPAL INVESTIGATOR: Dr. Steve Mathews** **INVESTIGATOR: Drs.Peter Kiama,MD and DrJoshua Kimani, MD** **STUDY CENTER:** University of Nairobi, Kenya

2. SYNOPSIS

NAME OF THE PRODUCT • RECEPTOL® Oral Spray
ACTIVE INGREDIENTS • RADHA 108 Series and Proline Rich Peptides (PRP)
TITLE OF THE STUDY • An Interventional / Prospective Phase II Accelerated Study To Determine The Efficacy & Safety Of RECEPTOL® Oral Spray Used as A Stand-Alone Mono Therapy in HIV / AIDS Patients with multiple symptoms
STUDY SITE • University of Nairobi, Kenya
PUBLICATION(S) • None
TREATMENT PERIOD • 90 days

OBJECTIVES

Primary Objective

To evaluate the efficacy of RECEPTOL® liquid in HIV/AIDS patients in terms of reduction in HIV viral load and HIV/AIDS related clinical symptoms.

Secondary Objectives

To determine the effect of oral spray administration of RECEPTOL® liquid on:

- Change in Body Weight of patients
- Absolute CD4 cell count
- Overall Assessment of Efficacy and Safety/Tolerability of RECEPTOL®

METHODOLOGY

- This trial was a 90 day, study to evaluate the Efficacy and Safety of RECEPTOL® liquid in HIV/ AIDS patients.
- The study was designed to investigate efficacy of RECEPTOL® therapy in reducing HIV viral load and HIV/AIDS related clinical symptoms.
- The study subjects received RECEPTOL® liquid as a spray self-administered by patients on either side of the oral buccal surface 3 times daily at every 4 hour's interval.

NUMBER OF PATIENTS

- A total of 30 patients completed the study.

INCLUSION CRITERIA

For recruitment in the study, the subjects were required to be :-

- If available, patients' pre-diagnoses report HIV seropositive.
- Patient who are symptomatic or asymptomatic.
- Patients who are ≥18 years of age.
- Patients who are willing to gain or maintain a proper diet and drink 5-8, 8 ounce glasses of water per day.

EXCLUSION CRITERIA

Patients were not included in the study if they were :-

- Patients treated with any other investigational drugs with 30 days before the study begins.
- Patients who are, think they might be or plan on becoming pregnant.

CRITERIA FOR EVALUATION

Safety

- Receptol® is a normal food substance and as such is as safe for human consumption as any other food. The safety of Receptol® has been further verified over the years by distributing it in the United States as a food product. .
- Since Receptol® is a food not a drug, metabolism and excretion are non-issues. There are no known drug interactions. The only contraindication identified thus far is intolerance to milk or milk products.

Efficacy

- Statistically significant reduction was observed in HIV Viral Load based on PCR measurement and an improvement in HIV/AIDS related clinical symptoms along with increase in body weight of the patients was observed at the end of treatment.
- There was a significant increase in Absolute CD4 count based on Flow Cytometry Analysis of blood.

STATISTICAL METHODS

- The clinical, Physical and laboratory measures obtained from the patients Symptom assessment from will be analyzed by appropriate descriptive and non-descriptive statistics.

STUDY RESULTS

Efficacy Results

- **HIV Viral Load based on PCR Diagnosis**: At the end of 90 Days Treatment (end of the study) with RECEPTOL®, mean Viral Load showed a significant reduction ($p<0.001$) from baseline as evident in the statistical analysis.
- **Absolute CD4 Cell Count:** At the end of 60 Days Treatment with RECEPTOL®, mean CD4 count showed significant increase, based on Flow Cytometry Analysis conducted at University of Nairobi.
- **Body Weight Gain**: A significant increase was evident in bodyweights of all the 30 HIV positive patients who completed the trial treatment.
- **Improvement In Clinical Symptoms**: There was a marked improvement in HIV associated clinical symptoms and many patients became asymptomatic at the end of 90 Days therapy At baseline, most of the patients exhibited symptoms of fatigue malaise however, all were asymptomatic at the end of treatment with RECEPTOL®. HIV associated Diarrhoea and Nausea was cured in all patients from 30 Days onwards with significant fall from 60 Days while a significant fall in HIV related Vomiting was seen in patients within 1st week of treatment with RECEPTOL®. Most of the patients became asymptomatic form 60 Days treatment onwards. There was a significant fall in the incidence of Fever, Cough and associated symptoms in most of the patients at the end of 1st week of treatment and all became asymptomatic after 3rd week onwards with the therapy.

Safety/Tolerability Results

- All patients tolerated RECEPTOL® well with NO Adverse or Serious Adverse Events reported.

CONCLUSION

- Because of differences in size, cohort profile and length of evaluation period, the study yielded a greater quantity of information that included positive clinical responses in three additional areas: hypertension, systemic lupus and tuberculosis. Several patients that had been bedridden for some time became ambulatory and were able to come to the clinic for continued participation in the study.

3. STATEMENT OF COMPLIANCE

This study was conducted in compliance with the Protocol as well as the Sponsor's and CRC's (CRO) **Standard Operating Procedures**. These were designed to ensure adherence with the ethical principles that have their origin in the **Declaration of Helsinki, Good Clinical Practice (GCP)** and applicable regulatory requirements.

4. LIST OF ABBREVIATIONS AND DEFINITIONS

List of Abbreviations

- **AIDS** Acquired Immunodeficiency Syndrome
- **ART** Anti-Retroviral Therapy
- **ARS** AIDS Related Complex
- **CD4** Cluster Of Differentiation 4
- **CD8** Cluster Of Differentiation 8
- **CHF** Congestive Heart Failure
- **CRC** Clinical Research Coordinator
- **CRO** Contract Research Organization
- **CDSCO** Central Drugs Standard Control Organization
- **cmm** Cubic Millimeter
- **DCGI** Drug Controller General of India
- **dL** Deciliter
- **ELISA** Enzyme Linked Immuno Sorbent Assay
- **GCP** Good Clinical Practice
- **HIV** Human Immunodeficiency Virus
- **INF** Interferon
- **mm3** Per cubic millimetre
- **ml** Millilitre
- **mg** Milligram
- **NABL** National Accreditation Board for Testing and Calibration Laboratories
- **NACO** National AIDS Control Organization
- **NKC** Natural Killer Cell
- **NNRTI** Non-Nucleoside Reverse Transcriptase Inhibitor
- **NRTI** Nucleoside Reverse Transcriptase Inhibitor
- **PCR** Polymerase Chain Reaction
- **PRP** Proline-Rich Polypeptide
- **TNF** Tumor Necrosis Factor
- **WHO** World Health Organization

Definitions of Terms

- **Eligible:** Qualified for enrolment into the study based on strict adherence to inclusion and exclusion criteria.
- **Evaluable:** Meeting all eligibility criteria, complying with the procedures defined in the Protocol and therefore included in analysis.
- **Investigator:** Treating physician
- **Protocol Amendment:** Any change in a study Protocol which affects the safety of subjects, the scope, design, assessments or scientific validity of the clinical investigation.
- **Subject(s):** Term used throughout this report to denote the enrolled individual(s)

5. TABLE OF CONTENTS

6. ETHICS COMMITTEE

This study was conducted in accordance with the ethical principles of Declaration of Helsinki. Ethical approval of the Study Protocol was obtained from the Local Ethics Committee at

Infectious Disease Clinic, where the study was conducted before the study was undertaken. The original documents were sent to Sponsor and the Investigator filed a copy. In addition, all local regulatory requirements will be adhered to. All attempts will be made to afford greater protection of study patients.

The Investigator/Institution has written and dated approval from the EC for the following: Study Protocol/Amendment(s), written Informed Consent Form including patient information sheet, consent form updates and patient recruitment procedures (e.g. advertisements)

7. INTRODUCTION

Introduction: HIV/AIDS and Types Of Treatment:

The advent of HIV/ AIDS has graphically demonstrated that our knowledge of viruses and how to treat viral infections was not adequate. According to the joint United Nations program on HIV / AIDS and World Health Organization (WHO), some 25 million people have died of HIV / AIDS in the past 25 years and an estimated 38.6 million are infected with the virus, making it one of the most lethal epidemic in the history of mankind.

Currently five classes of drugs are approved by US FDA for treatment of HIV infected patients. These five classes are Nucleoside Reverse Transcriptase Inhibitor (NRTI/NtRTI), Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI), Protease Inhibitor (PI), entry inhibitors and Integrase Inhibitor. Anti Retroviral Therapy (ART) regimen is complicated due to the high cost of treatment, poor compliance, pill burden, peculiar storage requirements, drug-drug interactions, co-morbidities like tuberculosis, liver disease, cardiovascular complications and importantly treatment failure due to resistance to drugs acquired by the virus through mutation. All the antiviral drugs developed so far to fight HIV infection, exhibit serious side effects like nausea, Diarrhoea, Vomiting, Pancreatitis, Anemia, Peripheral Neuropathy, Lactic Acidosis, Dyslipidemia and others. Currently, the US FDA has approved 29 drugs for use in the treatment of HIV Infection[5]. The presently available ART is very expensive. The future outlook for HIV / AIDS treatment from a pharmaceutical perspective remains bleak despite significant gains in understanding of the virus. This situation has forced scientists to look for alternative effective solutions.

A promising alternative which may prove more effective can be to stimulate the body's own defenses against the virus as well as the infected cells. Dietary supplementations of many naturally occurring substances have been claimed to boost human immunity by activating human Natural Killer (NK) cell activity.

One such area of investigation is based on an age-old remedy, the Colostrum, the first milk produced by a mammal following the birth of a newborn, which was widely used as an immunity booster and natural antibiotic before modern antibiotics were developed. Colostrum and various components of it have already been demonstrated to be useful in treating opportunistic infections associated with HIV/ AIDS such as Diarrhea etc. caused by Clostridium, Campylobacter and Amoeba spc.[13.] Specifically one of the components of Colostrums, the nano-peptides classified under Radha 108 series (Patent pending by Biomix Network Ltd.) and Proline

Rich Polypeptide (PRP) – Infopeptide has shown great promise. This unique polypeptide (a peptide fraction of whole Colostrum) has been shown to exhibit Immunomodulatory activity as well as antiviral activity[14]. It is the only Immunomodulator produced by mammals themselves for their progeny. The key factor is however, the protein fractionation and ultra filtration technology needed to extract Radha 108 and Proline-Rich Polypeptide (PRP) extraction which is developed now by Biomix Network Ltd using patented technology and molecular weight exclusion columns to ensure consistency of product batch after batch in every bottle of RECEPTOL®.

RECEPTOL®: Product Development Rationale

The application of RECEPTOL® is, in the medical field of Immuno-therapy which is a quiet revolution taking place in medicine. It is a form of treatment that uses the different aspects of your immune system, its cells and molecules and its various stratagems to tip the balance in your favor as your body battles to maintain health.

RECEPTOL® comes to us after nearly fifty years of research and over 3,500 scientific medical papers, which prove its effectiveness. It is found in colostrum and is a natural way of strengthening our immune systems against disease.

RECEPTOL® contains the Nano-Informational Peptides (RADHA108) and Proline-Rich Polypeptides (PRPs), derived from bovine Colostrum, which helps in strengthening the body's own immune system against diseases in a natural way.

The nano-polypeptides have been known for long for their antiviral, anti-inflammatory and immune enhancing properties. However, the molecular mechanism of their action in conjunction with low molecular weight nano-peptides was not known until *Dr. Theodore Damodar Singh*, an Applied Biochemist from University of California Irvine and Founder Director, Chaitanya Healthcare, India and Dr. Pawan Saharan, Chief Scientific Officer and Founder Director, Chaitanya Healthcare and Biomix Network Ltd., India identified and studied a series of *Nano-Informational Peptides (RADHA108$_{1-100}$)* from Bovine Colostrum.

The fusion of viral particles with human white blood cells occurs with the aid of glycoprotein epitopes on the viral wall. The informational proteins (RADHA108$_{1-100}$) in RECEPTOL® have been shown to mitigate cell fusion. The RADHA108$_{1-100}$ series of molecules may dock on the glycoprotein receptors of the viral surface mimicking their receptors on the cell surfaces and thus block the virus entry into the immune cells.

One of the Immunomodulatory action of RECEPTOL® is to stimulate the maturation of immature thymocytes into either helper or suppressor T cells[4,5], depending on the need of the body at a given time. Helper T cells present antigens (such as viral protein) to B lymphocytes, which in turn produce antibodies to that antigen[6]. Helper T cells also help produce memory T cells which retain the memory of an antigen in order to expedite the production of antibodies in the event the antigen is reencountered in the future[7].

Suppressor T cells, on the other hand, have been shown to deactivate other lymphocytes after an infection has been cleared to avoid damage to healthy tissues[8]. RECEPTOL® may also promote growth and differentiation of B cells in response to an infection[9] and the differentiation and maturation of macrophages and monocytes[10.] The activity of Natural Killer (NK) cells, cytotoxic cells of the innate immune system, is increased by up to 5-fold by RECEPTOL®[11, 12].

RECEPTOL® may modulate the cytokine system as well. Its constituents have been shown to stimulates the production of a wide range of cytokines, including the pro-inflammatory cytokines Tumor Necrosis Factor – Alpha (TNF-α) and Interferon Gamma (INF–γ) and anti-inflammatory cytokines Interleukin – 6 and – 10[13].

The constituents of RECEPTOL® may function as a molecular signaling device which works through receptors on target cell surfaces[14] to initiate or suppress the production of specific proteins. This property is not species specific[2]; and hence the constituents of RECEPTOL® derived from bovine Colostrum may work as effectively in humans too like the PRP of human Colostrum. There are no known side effects or drug interactions with the constituents of Colostrum, and it may be taken safely by patients of all ages. In an experimental in vitro system, the constituents of RECEPTOL® have been shown to effectively block HIV infection of cells[15.] RECEPTOL® in combination with Zidovudine®, a known anti-retroviral drug, has been shown to be effective in patients suffering from HIV/AIDS Related Complex (ARC), effecting an increase in White Blood Cells, CD8 lymphocytes and IL-2[16].

RECEPTOL® has shown to be effective in treating many different diseases and conditions including Allergies, Thrush, Diabetes (type II), Rheumatoid Arthritis, Corneal Regeneration, Diarrhoea, Hemolytic Anemia, Tuberculosis, HIV, Hepatitis A & C, Acute Viral Infections, Pharangitis (Viral), Viral Respiratory Infection, Plantar Warts, Colds and Flues, Herpes Simplex I & II etc.

Results of Previous Phase I

RECEPTOL® demonstrated in-field and clinical use with more that 10,000 HIV infants, children and adults in many countries. There have been no known exceptions to the ability to affect the progression of many chronic degenerative diseases for which it has been used. In many cases, the formula has induced what appears to be complete and lasting cellular recovery.
RECEPTOL® has shown to be effective in treating many different diseases and condition. However, it is prudent to focus attention on a few well-known diseases. Initially, Rheumatoid Arthritis was the selected disease to put under the microscope. The success of treating this autoimmune condition led to the selection of a high profile disease – HIV. RECEPTOL® has been used with positive results in more than 10,000 patients globally for HIV & other Viral infections, Tuberculosis, immunological diseases.

RECEPTOL® Phase I trial in Ohio, USA: This trial was conducted on 12 HIV patients with 30 days treatment and moderate control of product use. Results obtained from this trial were 10 out of 12 patients gained weight during the thirty-day trial period, of the 10 that gained weight, 7 (70%) gained an average of 6 lbs, 5 patients gained 6 lbs in one month, while 2 others 5.5 and 6.6 lbs respectively, the highest weight gain of 12 lbs was recorded for a patient who had been HIV positive since 1986 (10 years). 8 out of 10 patients had various levels of diarrhoea (mild, moderate or severe) at the beginning of the trial period. Out of the 8, 5 patients (62%) went from varying levels of diarrhoea severity to NO diarrhoea symptoms. The 1 patient without weight gain experienced total elimination of severe chronic diarrhoea and a return to solid stool formation. 8 out of 12 patients had various levels of nausea at the beginning of the trial period. Of the 8, 5 patients (62%) went from varying levels of severity of nausea symptoms to No nausea. Of the remaining 3 patients, with some degree of nausea, 2 experienced a reduction in the severity of their symptoms. 9 out of 10 patients, who reported fatigue symptoms at the beginning of the trial, experienced an increase in their level of energy. 3 out of 10 experienced a significant increase in energy, from initial varying levels of fatigue to NO fatigue. 4 out of 12 had either a mild to moderate cough at the beginning of the trial. 2 of the 4 reported NO cough at the end of the trail period. Of the remaining 2 individuals, 1 reported a reduction in the severity of his cough. All 12 patients experienced an improvement in their overall symptoms assessment score. The average reduction approached 2/3 (63%).
Since 1996, several improvements in the process engineering were made to increase the efficacy of RECEPTOL®.

8. STUDY OBJECTIVES

Primary Objective

To evaluate the efficacy of RECEPTOL® liquid in HIV/AIDS patients in terms of reduction in HIV viral load and HIV/AIDS related clinical symptoms.

Secondary Objective

To determine the effect of oral spray administration of RECEPTOL® liquid on:

- Change in Body Weight of patients
- Absolute CD4 cell count
- Overall Assessment of Efficacy and Safety/Tolerability of RECEPTOL®

9. INVESTIGATIONAL PLAN

Overall Study Design and Plan: Description

- This study was trial, comprised of a 90 days treatment period. Patient obtained RECEPTOL® supplies (to last the entire study).
- At the initial study visit, Informed Consent was signed by the patients and obtained. The patient's inclusion and exclusion criteria were reviewed. A brief physical examination was performed, to asses the severity of the disease and the patient's weight. A blood sample was withdrawn as directed by the physician.
- Information regarding the patient's survivability progression, weight, and performance statues was obtained and ill be recorded, and obtained on the Symptom Assessment Form provided.

Subject Selection Criteria

- The selection of subjects for this trial was based on the following Inclusion and Exclusion criteria.

INCLUSION CRITERIA

- If available, patients' pre-diagnoses report HIV seropositive.
- Patient who are symptomatic or asymptomatic.
- Patients who are ≥18 years of age.
- Patients who are willing to gain or maintain a proper diet and drink 5-8, 8 ounce glasses of water per day.

EXCLUSION CRITERIA

Patients were not included in the study if they were :-

- Patients treated with any other investigational drugs with 30 days before the study begins..
- Patients who are, think they might be or plan on becoming pregnant.

Treatment Procedures

- RECEPTOL® liquid spray used in the study was a Colostrum product, containing natural microscopic molecules of RADHA108 of 800 – 1200 Dal molecular weight (below 2000 DaL that enable to cross bbb- Blood brain barrier) and PRPs consisting of oligoribonucleotides attached to a peptide molecule. RECEPTOL® was manufactured by Biomix Network Ltd., Mumbai by protein fractionation technology and ultra nano filtration the only nanotechnology based plant in India. Eligible patients were evaluated for medical history, physical examination, blood and urine tests, and other tests as determined by the Principal Investigator. Patients had received RECEPTOL® liquid in pump spray form and were taught to self-administer the medication. The frequency of dose administration was 3 sprays at every 4 hour intervals directly on the buccal mucosa (inner cheek).The patients were advised to gargle the medication in the mouth for 30 seconds before swallowing it. Each pump of the spray device delivered 0.7ml of RECEPTOL® liquid. The trial treatment as described above was continued for a period of 90 days.

Compliance

- Each patient self administered 5 sprays (each measuring 0.75 ml of the liquid) of RECEPTOL® liquid, daily, at 4 hourly intervals. They were advised to have a 6 hrs sleep, at a time, to facilitate 6 hourly medication and were also advised to follow a regular daily exercise.
- Patients were instructed to spray the study drug in mouth and allow it to circulate in mouth for 30 seconds and then swallow it.
- Patients were asked to follow a well balanced diet of 40% Carbohydrates, 30% Protein, 30% Fats and Oils, to drink plenty of clean fresh water and avoid any such food that may cause increased gastric acidity.

Blinding/Randomization Technique

- Not Applicable

Assessment of Efficacy and Safety/Tolerability Criteria

- Blood Samples to assess the HIV Viral Load, CD4 cell count and other laboratory parameters including Haemoglobin, White Blood Corpuscles Count (WBC), Liver Function Tests (LFT) and Renal Function Tests (RFT) were collected at baseline and end of treatment.
- HIV Viral Load was assessed on basis of PCR Diagnosis while CD4 cell count were based on Flow Cytometry Analysis.
- Clinical symptoms and Physical Findings which included HIV associated Fatigue Malaise, Diarrhoea, Nausea, Vomiting, Fever, Cough, Sleep Disturbance etc were assessed using Symptom Assessment Form which was recorded in patients every visit.
- Safety parameters were assessed by measuring the no. of Adverse and Serious Adverse Events

Statistical Methods Used

- The clinical, Physical and laboratory measures obtained from the patients Symptom Assessment form will be analyzed by appropriate descriptive and non-descriptive statistics.

10. TRIAL SUBJECTS

A total of 30 patients were enrolled and all completed study without any drop-out. Thus, at the end of study, pre and post treatment data of 30 patients mentioning clinical symptoms and biochemical profile including CD4 cell count and HIV Viral Load were available for analysis.
(Total no. of Patients Enrolled and Analyzed = 30)

11. STUDY RESULTS

***Table Showing Clinical Symptoms Score from Baseline to the End of Treatment with* RECEPTOL®**

	Initial	30 days	60 days	90 days
Total Patient Reported	35	31	20	17
Score	6.1	1.8	1.2	1.3
Percent Reduction		69	80	79

***Table Showing Physical Findings Score from Baseline to the End of Treatment with* RECEPTOL®**

	Initial	30 days	60 days	90 days
Total Patient Reported	30	27	13	13
Score	4.0	2.5	2.1	1.6
Percent Reduction		38	49	60

Table Showing Reduction/Elimination of Symptoms of Diarrhoea in Patients from Baseline to End of Treatment (Day 90)

Diarrhoea	30 Day		
	Total	Reduction	Elimination
Patients Reporting	16	14	14
Percent of Total		87.5	87.5

Diarrhea	60 Day		
	Total	Reduction	Elimination
Patients Reporting	6	6	6
Percent of Total		100	100

Diarrhea	90 Day		
	Total	Reduction	Elimination
Patients Reporting	5	5	5
Percent of Total		100	100

Figure 1: Reduction in Number of Patients with Diarrhoea during the 90 Days Trial Treatment with RECEPTOL®

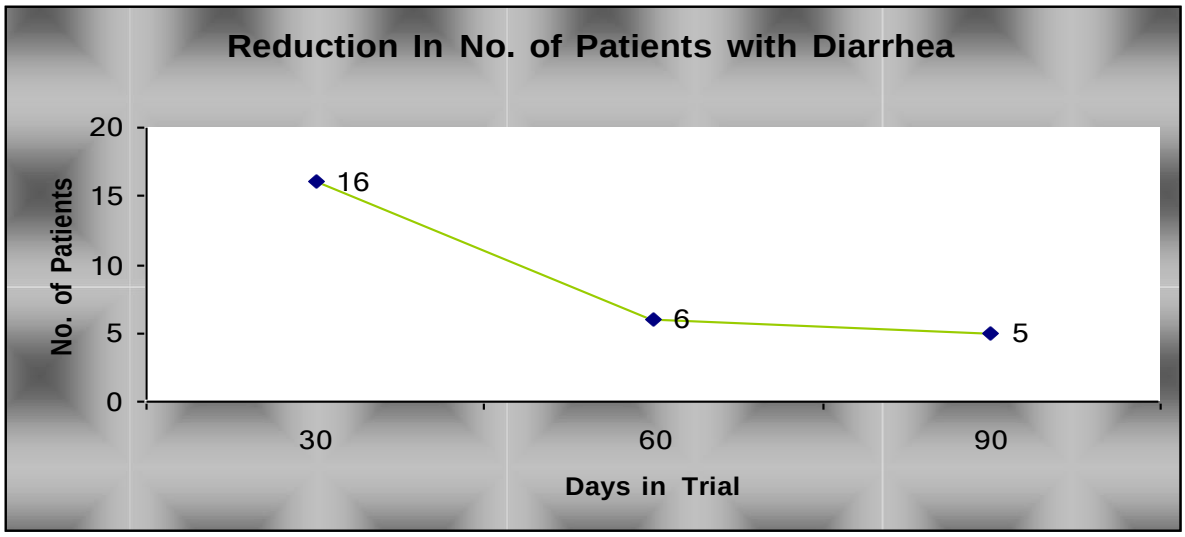


Table Showing Reduction/Elimination of Symptoms of Nausea in Patientsfrom Baseline to End of Treatment (Day 90)

Nausea	30 Day		
	Total	Reduction	Elimination
Patients Reporting	25	22	11
Percent of Total		88	80

Nausea	60 Day		
	Total	Reduction	Elimination
Patients Reporting	12	10	10
Percent of Total		83	83

Nausea	90 Day		
	Total	Reduction	Elimination
Patients Reporting	10	9	9
Percent of Total		90	90

Figure 2: Reduction in Number of Patients with Nausea during the 90 Days Trial Treatment with RECEPTOL®

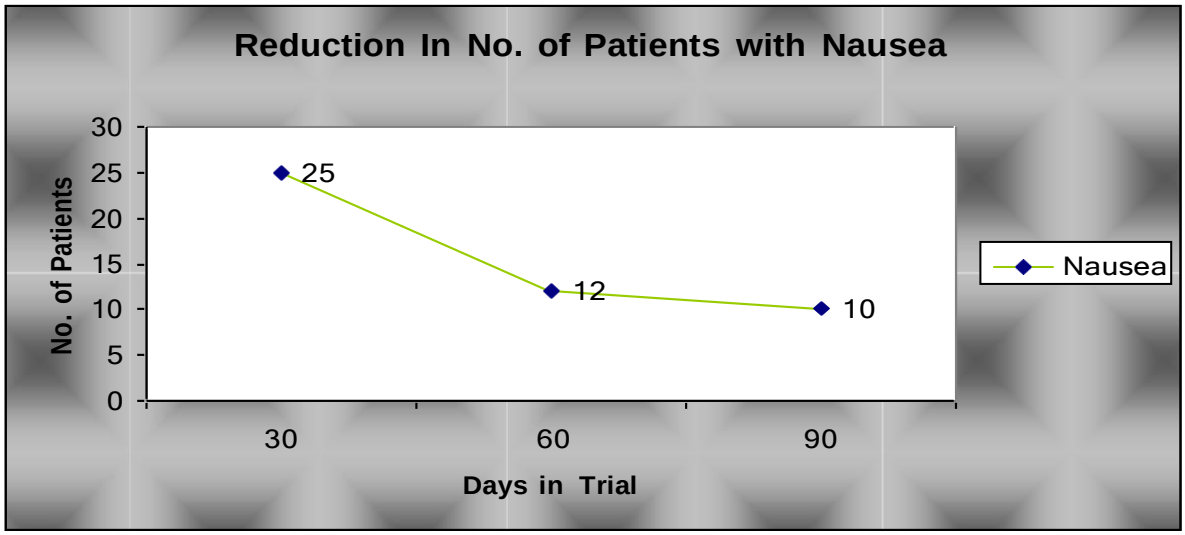


Table Showing Reduction/Elimination of Symptoms of Diarrhoea inPatients from Baseline to End of Treatment (Day 90)

Vomiting	30 Day		
	Total	Reduction	Elimination
Patients Reporting	4	4	3
Percent of Total		100	75

Vomiting	60 Day		
	Total	Reduction	Elimination
Patients Reporting	2	2	2
Percent of Total		100	100

Vomiting	90 Day		
	Total	Reduction	Elimination
Patients Reporting	1	1	1
Percent of Total		100	100

Figure 3: Reduction in Number of Patients with Vomiting During the 90 Days Trial Treatment with RECEPTOL®

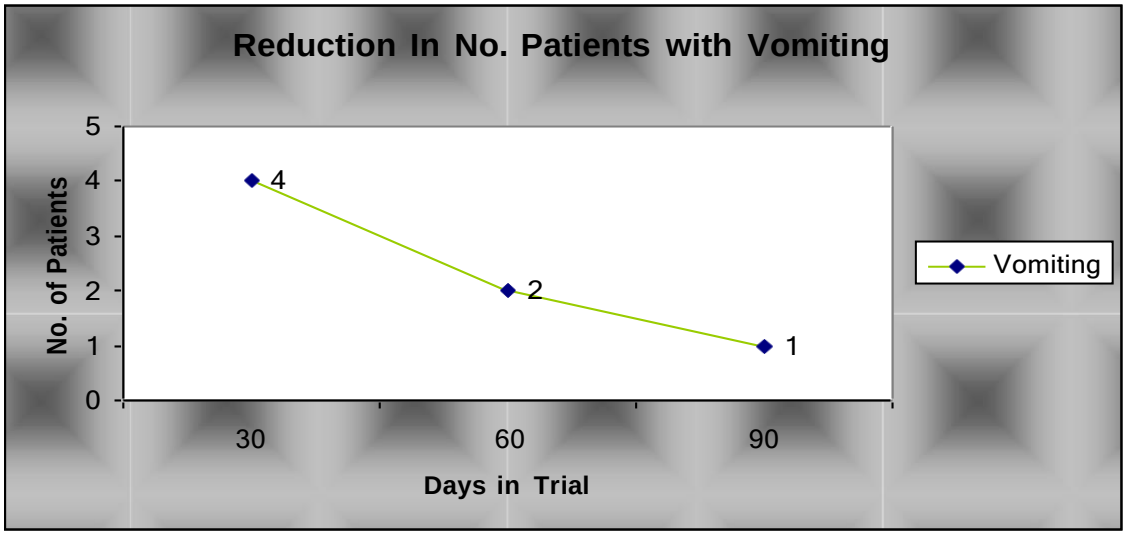


Table Showing Reduction/Elimination of Symptoms of Fever in Patientsfrom Baseline to End of Treatment (Day 90)

Fever	30 Day		
	Total	Reduction	Elimination
Patients Reporting	8	6	6
Percent of Total		75	75

Fever	60 Day		
	Total	Reduction	Elimination
Patients Reporting	5	4	4
Percent of Total		80	80

Fever	90 Day		
	Total	Reduction	Elimination
Patients Reporting	5	4	4
Percent of Total		80	80

Figure 4: Reduction In Number of Patients with Fever During the 90 Days Trial Treatment with RECEPTOL®

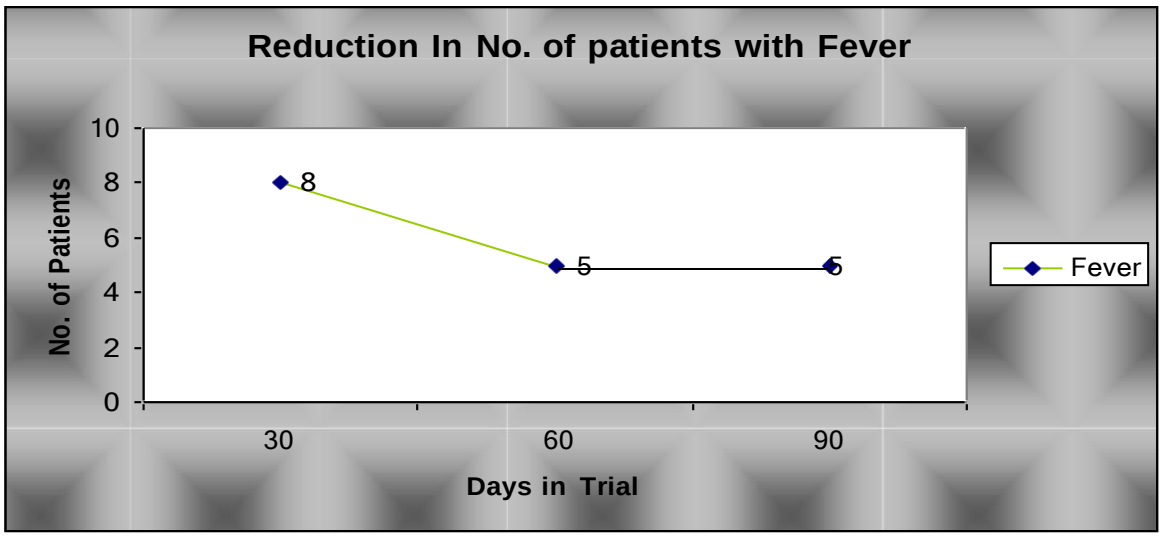


Table Showing Reduction/Elimination of Symptoms of Cough In Patientsfrom Baseline to End of Treatment (Day 90)

Cough	30 Day		
	Total	Reduction	Elimination
Patients Reporting	10	7	6
Percent of Total		70	60

Cough	60 Day		
	Total	Reduction	Elimination
Patients Reporting	7	5	5
Percent of Total		71	71

Cough	90 Day		
	Total	Reduction	Elimination
Patients Reporting	4	2	2
Percent of Total		50	50

Figure 5: Reduction in Number of Patients with Cough during the 90 Days Trial Treatment with RECEPTOL®

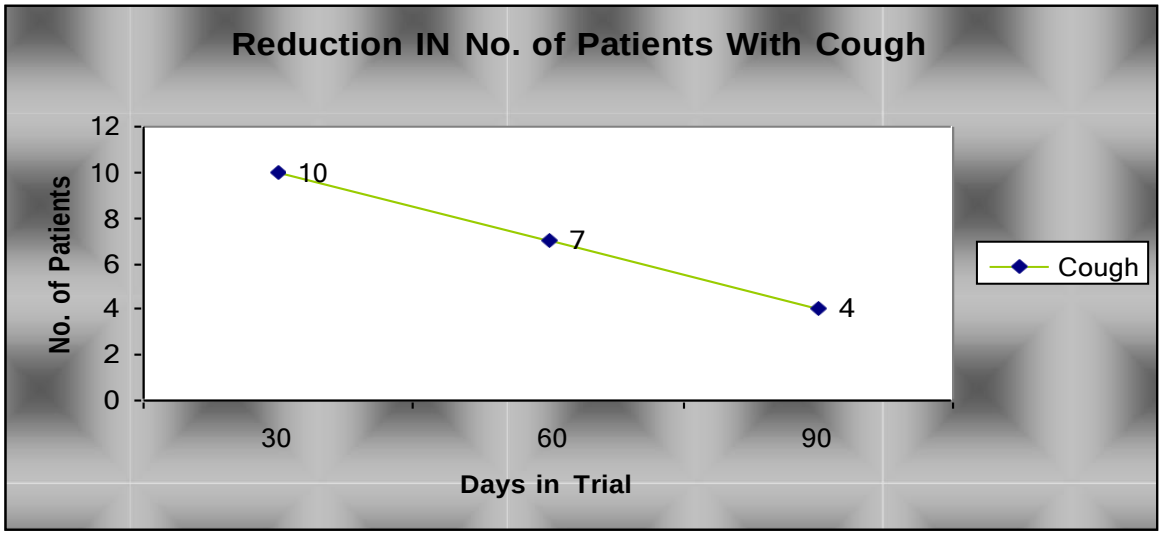


Table Showing Reduction/Elimination of Symptoms of Tuberculosis inPatients from Baseline to End of Treatment (Day 90)

Tuberculosis	30 Day		
	Total	Reduction	Elimination
Patients Reporting	3	3	2
Percent of Total		100	67

Tuberculosis	60 Day		
	Total	Reduction	Elimination
Patients Reporting	2	2	2
Percent of Total		100	100

Tuberculosis	90 Day		
	Total	Reduction	Elimination
Patients Reporting	2	2	2
Percent of Total		100	100

Figure 6: Reduction in Number of Patients with Tuberculosis during the 90 Days Trial Treatment with RECEPTOL®

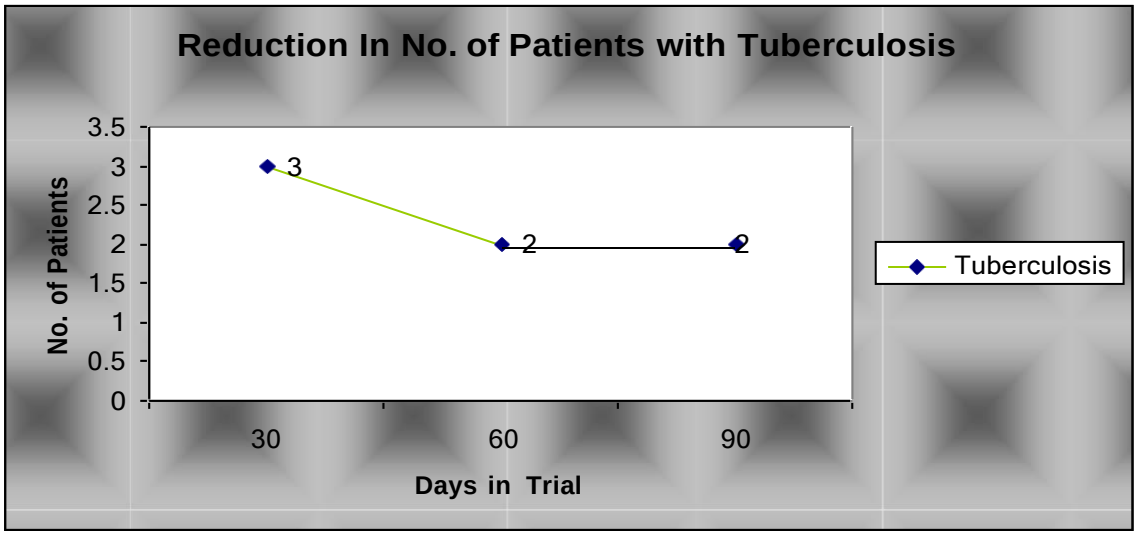


Table Showing Reduction/Elimination of Symptoms of Fatigue/Malaise inPatients from Baseline to End of Treatment (Day 90)

Fatigue / Malaises	30 Day		
	Total	Reduction	Elimination
Patients Reporting	23	23	18
Percent of Total		79	62

Fatigue / Malaises	60 Day		
	Total	Reduction	Elimination
Patients Reporting	17	14	14
Percent of Total		82	82

Fatigue / Malaises	90 Day		
	Total	Reduction	Elimination
Patients Reporting	16	12	12
Percent of Total		75	75

Figure 7: Reduction in Number of Patients with Fatigue/Malaise during the 90 Days Trial Treatment with RECEPTOL®

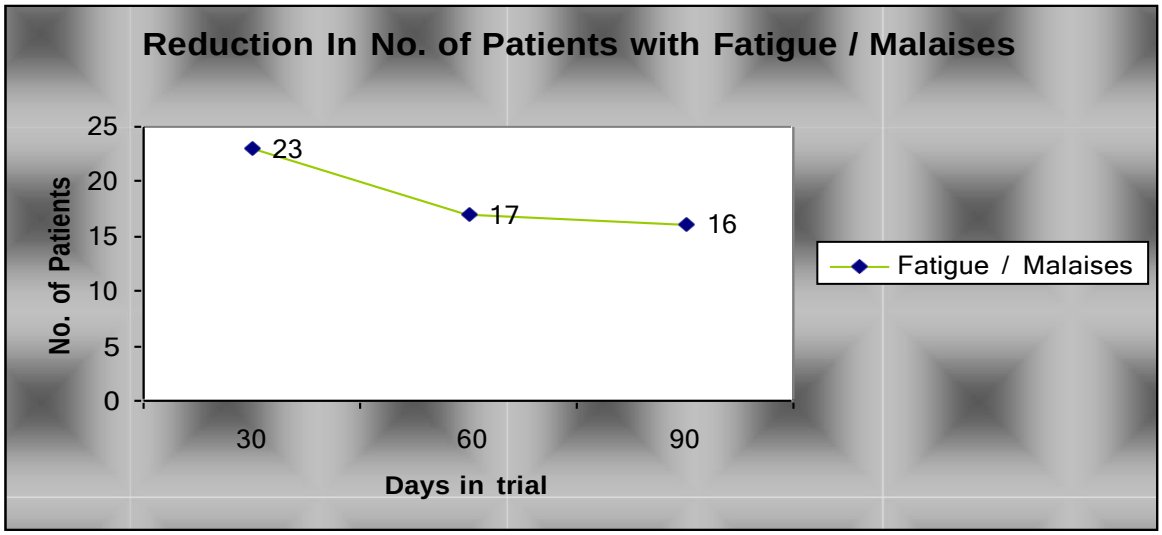


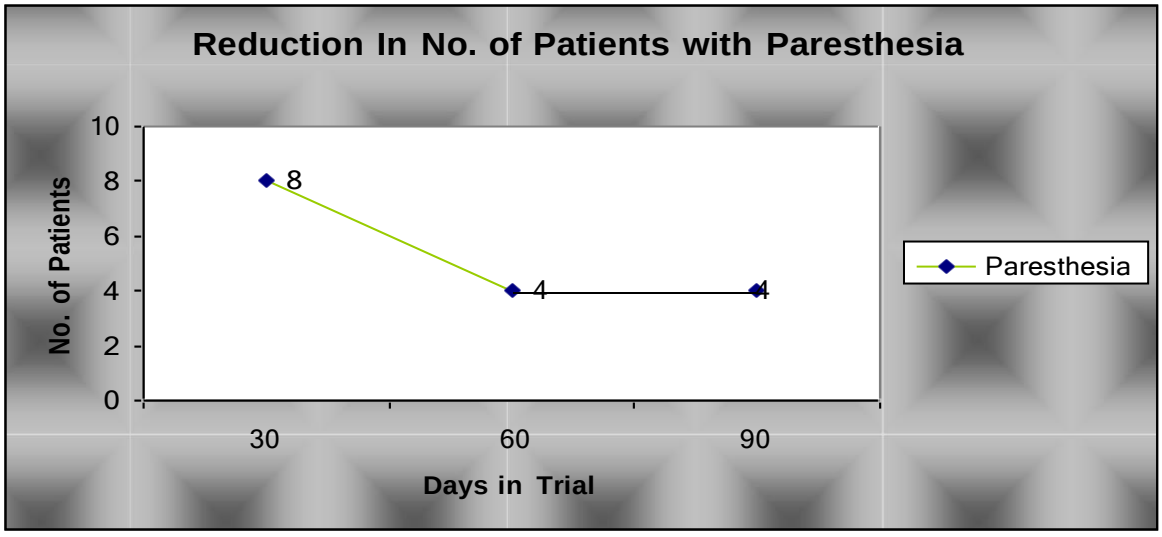
Table Showing Reduction/Elimination of Symptoms of Paraesthesia inPatients from Baseline to End of Treatment (Day 90)

Paraesthesia	**30 Day**		
	Total	**Reduction**	**Elimination**
Patients Reporting	8	6	5
Percent of Total		75	62

Paraesthesia	**60 Day**		
	Total	**Reduction**	**Elimination**
Patients Reporting	4	4	4
Percent of Total		100	100

Paraesthesia	**90 Day**		
	Total	**Reduction**	**Elimination**
Patients Reporting	4	4	4
Percent of Total		100	100

Figure 8: Reduction in Number of Patients with Paraesthesia during the 90 Days Trial Treatment with RECEPTOL®



Safety Evaluation

- Safety/Tolerability assessments consisted of monitoring and recording all Adverse Events and Serious Adverse Events. All patients tolerated RECEPTOL® well with no side effects. Milk allergies are caused by the large milk proteins, primarily casein, and to a lesser extent the Immunoglobulins. These proteins are completely removed from the RECEPTOL®. As RECEPTOL® is a food substance derived from Colostrum, it was found to be safe for human consumption.

12. DISCUSSION AND OVERALL CONCLUSIONS

This trial was conducted in 30 HIV patients with 90 days treatment and moderate control of product use. The objectives of this study were to demonstrate, under clinical conditions, the Efficacy and Safety of Infoprotein supplementation in patients known to have advanced disease (HIV/AIDS), compromised immune resources and limited access to conventional treatment.

Positive clinical results were observed in the Nairobi patients. The results demonstrated that the product appeared to be free of side effects and generally well tolerated by the participants. Some signs, consistent with detoxification, were noted but resolved when the patients increased their water consumption. The product demonstrated significant value by reducing or resolving the symptoms of opportunistic infections most commonly associated with the dynamic of HIV/AIDS. Patients often experienced weight gains as part of an overall pattern of positive response.

Conclusion: Because of differences in size, cohort profile and length of evaluation period, the Nairobi study yielded a greater quantity of information that included positive clinical responses in three additional areas: hypertension, systemic lupus and tuberculosis. Several patients that had been bedridden for some time became ambulatory and were able to come to the clinic for continued participation in the study.

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