Clinical Trial Details (PDF Generation Date :- Tue, 18 Jun 2019 17:22:08 GMT)

CTRI Number	CTRI/2013/09/003963 [Registered on: 06/09/2013] - **Trial Registered Prospectively**
Last Modified On	17/06/2014
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug
Study Design	Randomized, Parallel Group, Active Controlled Trial
Public Title of Study	Study to compare the safety and efficacy of etanercept of Intas Biopharmaceuticals Ltd against Enbrel® in patients with Active Rheumatoid Arthritis
Scientific Title of Study	A Prospective, Comparative, Open Label, Randomized, Multicentric Phase III study to compare the safety and efficacy of etanercept of Intas Biopharmaceuticals Ltd against Enbrel® in patients with Active Rheumatoid Arthritis

Secondary IDs if Any

Secondary ID	Identifier
IBPL_ET_01_Version 2.0_Dated 17/04/2013	Protocol Number

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr Naman H Shah
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Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
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Email	naman_shah@intaspharma.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> NA

Primary Sponsor

Primary Sponsor Details	
Name	Intas Biopharmaceuticals Limited
Address	423/P/A, Sarkhej-Bavla Highway, Moraiya, Tal: Sanand
Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Uma Kummar	All India Institute of Medical Sciences (AIIMS)	Ansari Nagar – 110029 New Delhi DELHI	011-26594467 umaakumar@yahoo.co.in
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Dr Symasis Bandopadhyay	Apollo Glaneagles Hospitals	Internal Medicine & Rheumatology, 58, Canal circular road–700054,India Kolkata WEST BENGAL	03323203040 sambando@yahoo.co.uk
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		MAHARASHTRA	
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Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
AMC MET Ethics Committee, L.G.Hospital, Ahmedabad (Dr Bhavesh Jesalpura)	Approved	19/07/2013	No
Apollo Glaneagles Hospitals Institutional Ethics Committee, Kolkata,Dr. Symasis Bandopadhyay	Approved	05/10/2013	No
Ethics Committee of Care Institute of Medical Sciences, Ahmedabad (Dr Yakshat Shah)	Approved	16/07/2013	No
Ethics Committee Sir Ganga Ram Hospital, New Delhi (Dr. Lalit Duggal)	Approved	01/10/2013	No
Hatkesh Healthcare Foundation Ethics	Approved	12/06/2013	No

Committee, Junagadh (Dr M M Dolakia)			
Institute Ethics Committee, New Delhi (Dr. Uma Kumar)	Approved	23/09/2013	No
Institutional Ethics Committee B.J. Medical College & Civil Hospital, Ahmedabad,Dr. A N Shah	Approved	25/10/2013	No
Institutional Ethics Committee Maulana Azad Medical College and Associated Lok Nayak, New Delhi (Dr. Suresh Kummar)	Approved	14/11/2013	No
Institutional Ethics Committee, Institute of Post Graduate Medical Education & Research, Kolkata (Dr Geetabali Sircar)	Approved	27/07/2013	No
Jasleen Hospitals Ethics Committee, Nagpur,Dr. Smriti Ramteke	Approved	02/09/2013	No
Nirmal Hospital Pvt Ltd Ethics committee, Dr. Bankim Desai	Approved	14/09/2013	No
PENTA-MED Ethics Committee, Pune (Dr Girish Gokuldas Bhatia)	Approved	26/06/2013	No
Sapthagiri Institute of Medical Sciences & Research Centre Institutional Ethics Committee, Karnataka,Dr. Arun M S	Approved	07/08/2013	No
Sushruta Hospital Ethics Committee,Hubli, Dr. Vikram Haridas	Approved	29/08/2013	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	16/08/2013

Health Condition / Problems Studied

Health Type	Condition
Patients	Active Rheumatoid Arthritis

Intervention / Comparator Agent

Type	Name	Details
Intervention	Etanercept	25 mg subcutaneous injection twice a week for 12 weeks
Comparator Agent	Enbrel®	25 mg subcutaneous injection twice a week for 12 weeks

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	65.00 Year(s)
Gender	Both

Details	Patients with active Rheumatoid Arthritis diagnosed according to the revised 1987 American College of Rheumatology (ACR) criteria for the classification of rheumatoid arthritis Subjects with Global Functional Status Assessment - class I, II or III according to the revised criteria of the American College of Rheumatology (ACR)

Exclusion Criteria

Exclusion Criteria	
Details	1. Previous treatment with DMARDs except methotrexate 2. Known hypersensitivity to etanercept or any of the components of study medication 3. Patients with history of tuberculosis in the past or having findings suggestive of active tuberculosis or latent tuberculosis 4. Pregnant or breast-feeding patients 5. History of blood dyscrasias 6. Patients with history of alcohol, drug or chemical abuse 7. Any history or presence of clinically significant cardiovascular, respiratory, hepatic, renal, hematologic, gastrointestinal, endocrine, immunologic, dermatologic, cancer, uncontrolled diabetes, neurologic or psychiatric disease or any other condition which, in the opinion of the investigator, would jeopardize the safety of the subject or the validity of the study results

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Other
Blinding/Masking	Open Label

Primary Outcome

Outcome	Timepoints
Percentage of patients achieving a 20% ACR response rate	at 12 weeks

Secondary Outcome

Outcome	Timepoints
Percentage of patients achieving a 50% ACR response rate	at 12 weeks
Mean change in DAS28 score and HAQ score from baseline	at 12 weeks

Target Sample Size	**Total Sample Size=**100 **Sample Size from India=**100
Phase of Trial	Phase 3
Date of First Enrollment (India)	28/10/2013
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**1 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	None Yet
Brief Summary	Rheumatoid arthritis occurs in approximately 1% of the adult population and is associated with progressive joint destruction, functional disability, and decreased life expectancy. Disease modifying antirheumatic drugs (DMARDs), such as methotrexate, sulfasalazine, and hydroxychloroquine, may retard disease progression. However, many patients do not achieve an adequate response, and many do not maintain a response because of toxicity or lack of efficacy. Although the underlying cause of rheumatoid arthritis is unknown, tumor necrosis factor TNF-a, a proinflammatory cytokine produced by macrophages and T cell contributes to the pathogenesis of synovitis and joint destruction. Because of the involvement of TNF in the pathogenesis of rheumatoid arthritis, it was hypothesized that soluble recombinant human TNF receptors might be useful as therapy for this disease. Etanercept is a recombinant human TNF receptor Fc fusion protein, fused to the Fc portion of human IgG1. Previous trials in patients with active rheumatoid arthritis who had an inadequate response to DMARDs have shown etanercept to be safe, well tolerated, and able to produce significant dose-dependent improvements in disease activity. The innovator product Enbrel marketed by Wyeth Limited has recently been approved by various regulatory including the US Food and Drug Administration (FDA), European and DCGI for treatment of RA.

Intas Biopharmaceuticals Ltd (IBPL) has developed biosimilar product etanercept. IBPL had already conducted non-clinical studies of test product to prove safety profile of test product at human intended dose. The current study is planned to compare the safety and efficacy of etanercept manufactured by Intas Biopharmaceuticals Limited against the comparator product Enbrel for the treatment of Active Rheumatoid Arthritis patients.