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Assessing ExemptiaTM as a potential treatment for rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and juvenile idiopathic arthritis

Submission date
23/01/2019

Recruitment status
No longer recruiting

Registration date
06/02/2019

Overall study status
Completed

Last Edited
02/12/2019

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Adalimumab is a fully human IgG1 monoclonal antibody with high specificity for TNF. Adalimumab (HUMIRA), the fully human anti-TNF alpha monoclonal antibody, was first approved globally in 2002 and has since then been the most preferred therapy to treat patients suffering from auto immune disorders. However, the therapy was not available to patients in India.

In India, Cadila Healthcare Limited has developed a biosimilar of Adalimumab (ExemptiaTM). ExemptiaTM(Adalimumab) has received marketing approval on 9th December 2014 to prescribe for the treatments of Rheumatoid arthritis, Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Crohn's Disease, Hidradenitis Suppurativa and Plaque Psoriasis.

Biosimilars have a similar level of efficacy and safety compared to that of the originator products and provide additional advantage to patients in terms of affordability and accessibility.

The main objective of this ASPIRE registry is to develop and maintain a robust patient registry /repository in order:
1. To evaluate the efficacy and safety of ExemptiaTM (Adalimumab) in patients suffering with Rheumatoid arthritis, Ankylosing Spondylitis, Psoriatic Arthritis and Juvenile Idiopathic Arthritis.
2. To provide and further strengthen the evidence base for ExemptiaTM (Adalimumab) to benefit patients suffering from such rheumatic disorders.

Who can participate?
Participants are Both male or female patient ≥2 years or upto 75 years diagnosis with Rheumatoid Arthritis (RA)/Ankylosing Spondylitis (AS)/Psoriatic arthritis (PsA)/Juvenile Idiopathic Arthritis (JIA) as per speciality physician judgement and have been prescribed Exemptia

What does the study involve?
A total 1500 patients with rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and juvenile idiopathic arthritis who are deemed fit as per screening requirements to be started on Exemptia therapy. Those who give consent to enroll in study would be followed up as per the physician recommendations while on therapy and 6 months post therapy stoppage. While on therapy and post the therapy stoppage the lab tests ordered by physician in his routine practice shall be collected during follow ups. Only the routine investigations ordered by physician for each indication would be ordered and no special tests would be ordered for this study.

Standard Adalimumab (Exemptia) 40 mg every other week dosing regimen will be given to the patients.

All the patients will be assessed for disease activity, change in rheumatic disease symptoms, Inflammation, pain, physical function and health assessment using various tools.

Safety of patients would be monitored with Side effect profile basis regular tests and monitoring by physician.

What are the possible benefits and risks of participating?
The possible benefit of participating is that the Adalimumab biosimilar (Exemptia) can be as effective as its originator. There are no known risks to participants, and they will be monitored for any side effects through routine physical and laboratory examinations every 3 months.

Where is the study run from?
The study will be conducted various research centers across India.

When is the study starting and how long is it expected to run for?
30/11/2015 to 30/11/2019

Who is funding the study?
The study is funded by Cadila Healthcare limited Ahmedabad.

Who is the main contact?
Dr Mihir Gharia
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Contact information

Type(s)
Scientific

Contact name
Dr Mihir Gharia

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Additional identifiers

Protocol serial number
Exemptia Registry Protocol; Version 2.0

Study information

Scientific Title
Post-marketing observational study to follow-up patients with rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and juvenile idiopathic arthritis who are treated with ExemptiaTM (Adalimumab).

Acronym
ASPIRE

Study objectives
The main objective of this ASPIRE registry is to develop and maintain a robust patient registry /repository in order:
1. To evaluate the efficacy and safety of ExemptiaTM (Adalimumab) in patients suffering with rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and juvenile idiopathic arthritis.
2. To provide and further strengthen the evidence base for ExemptiaTM (Adalimumab) to benefit patients suffering from such rheumatic disorders.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Intersystem Biomedica Ethics Committee, 09/02/2018, ref. ISBEC/NR-3/DD-JJ/2018.

Study design
Observational, post marketing study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Rheumatoid Arthritis, Ankylosing Spondylitis, Psoriatic Arthritis and Juvenile Idiopathic Arthritis

Interventions
This is a real world observational study in which patients at different centers post their diagnosis of either of IMID’s and starting of Exemptia as a therapy to them, come for follow up as per the physician’s setting. The physician prescribes Adalimumab Bisoimilar for treatment duration as per his choice (which happens with biologics in India since they are used as for short duration

because of cost concerns). Since there is no intervention to normal clinical practice, the observations were recorded of their different parameters whenever the physician requested them for follow up visits. This enables a free non formalized way of data collection and real world experience. The observations and values are captured as long as patient comes for follow up while on therapy and 6 months post discontinuation of therapy.

ExemptiaTM (Adalimumab) 40 mg every other other week(q2wk) via subcutaneous route as per the prescribing information of ExemptiaTM(Adalimumab) in case of Adults and For ≥2 years
10 kg to <15 kg: 10 mg SC q2wk
15 kg to <30 kg: 20 mg SC q2wk
≥30 kg: 40 mg SC q2wk

Baseline and follow-up data will be captured at least for 2, 4, 8, 12, 16, 24, 52 week ± 1.

Intervention Type
Biological/Vaccine

Primary outcome(s)
Timeframe: baseline, and week 24.
1. Change in rheumatoid arthritis symptoms was measured using ACR20
1.1. Swollen joint count
1.2. Tender joint count and median of these 3 parameters ESR/VAS/PGA showing at least 20% improvement
2. Disease Outcome Measures for RA & AS
2.1. Reduction in DAS28 for RA
2.1.1. Swollen joint count
2.1.2. Tender joint count
2.1.3. Patient global assessment
2.1.4. Erythrocyte sedimentation rate
2.2. Reduction in BASDAI for AS-Questionnaire based outcome measure
3. Symptomatic improvement was measured using the reduction in pain VAS score.
4. Inflammation was measured using the reduction in Acute Phase Reactants-ESR/CRP
5. Tolerability was measured using patients 4 point assessment questionnaire

Key secondary outcome(s))
Timeframe: baseline, and week 24.
1. Change in rheumatoid arthritis symptoms was measured using ACR50, ACR70
2. Disease severity was measured using physician global assessment
3. Patient reported outcome was measured using patient global assessment
4. Drug Safety was measured using:
4.1. Frequency and severity of adverse events
4.1.1. Adverse events as reported by the physician CIOMS form for serious AE
4.2. Physical Examination
4.3. Vital Signs
4.4. Laboratory parameters

Completion date
30/11/2019

Eligibility

Key inclusion criteria
1. ≥2 years up to 75 years old
2. Diagnosis as per current guidelines published by ACR/EULAR/CASPAR/ILAR guidelines of:
2.1. Rheumatoid Arthritis
2.2. Ankylosing Spondylitis
2.3. Psoriatic arthritis
2.4. Juvenile Idiopathic Arthritis (JIA)
3. Treatment with ExemptiaTM (Adalimumab)
4. Subjects and/or their parent/ legal guardian were willing to be contacted in the future by study staff.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
All

Sex
All

Total final enrolment
149

Key exclusion criteria
1. Subjects receiving Adalimumab other than ExemptiaTM (Adalimumab)
2. Any contraindication for ExemptiaTM (Adalimumab) or concomitant drug like CNS and myeloid disorders according to Prescribing Information

Date of first enrolment
30/11/2015

Date of final enrolment
30/11/2015

Locations

Countries of recruitment
India

Study participating centre
Sarvajeet Pal
Apollo Hospitals Road Number 72, Landmark: Opposite to Bharatiya Vidya Bhavan School Lane & Near Film Nagar, Hyderabad Telangana
Hyderabad
India
500033

Study participating centre
Manjari Agarwal
AC-52, Second Floor, Tagore Garden, -
New Delhi
India
110060

Study participating centre
Ajit Nalawade
PAIN & ARTHRITIS CLINIC, F-204, Choice-A apartments, 38, Sassoon road, Near Ruby Hall Clinic,
Pune
India
410001

Study participating centre
Vijay Rao
Divisha Arthritis and Medical Center, No- 500/A, 1st G Cross, 8th Main Road,4th Block, 3rd Stage,
, Landmark: St. Mira's High School Basaveshwaranagar , Bangalore
Bangalore
India
560079

Study participating centre
Smruti Ramteke
Jasleen Hospital, Opp. Big Bazar, Panchsheel Square, Dhantoli,
Nagpur
India
440001

Study participating centre
Lalit Duggal
C-2/ 252, Janakpuri, New Delhi -
delhi
India
110058

Study participating centre

Sanjeev Kapoor
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Delhi
India
110058

Study participating centre
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Brij Medical Centre KK-54, Kavi Nagar, Ghaziabad. (U.P.)
ghaziabad
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110095

Study participating centre
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AB Rheumatology Centre 5-9-1032/A, Bhartiya Vidya Bhavan Rd, Gun Foundry, Basheer Bagh, Hyderabad, Telangana
hyderabad
India
500001

Study participating centre
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Apex Institute Of Medical Sciences, 1219, Santoshpur, -
Kolkata
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700075

Study participating centre
Varsha Bagul
201, A Wing, 2nd Floor, Swapan Bhoomi Building, S K Bole Road, Above Bharat Bank, Nearby Portuguese Church, ,
Dadar West
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400014

Study participating centre
Shashank Akerkar
Mumbai Arthritis Clinic & Research Center WING-K, Lal Bahadur Shastri Rd, Rajiv Gandhi Nagar, Bhandup West, Mumbai, Maharashtra

Bhandup West, Mumbai,
India
400078

Study participating centre
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10/75, 3rd Floor, Old Rajinder Nagar, New Delhi-110060
delhi
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110060

Study participating centre
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201009

Study participating centre
Ashish Badika
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Indore
India
25111

Study participating centre
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mumbai
India
400004

Study participating centre
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Jaipur Arthritis Centre H 7, Jan Path, Sector 10, Sector 6, Shyam Nagar, , Rajasthan
Jaipur
India
302019

Study participating centre
Arindam Royl
Yashoda Hospital Alexander Road Secunderabad , Andhra Pradesh , India
secunderabad
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500026

Study participating centre
Raja Natarajan
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vellore
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632011

Study participating centre
Viswanath Kaushik
Arthritis & Rheumatism Centre 17 Jambulingam Street Nungambakkam
Chennai
India
600034

Study participating centre
Sujata Sawhney
Sir Ganga Ram Hospital Center for Child Health, Sir Ganga Ram Hospital, New Delhi, Delhi
delhi
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Krishnamurthy Venkataraman
Apollo Speciality Hospital 320,Anna Salai , Anna Salai Chennai -
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Study participating centre
Banwari Sharma
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jaipur
India
302006

Study participating centre
Shiva Prasad
Kuvempu Nagar 1st Stage, Kuvempu Nagara, Mysuru, Karnataka
Mysuru,
India
570008

Study participating centre
Subramanian Nallasivan
Velammal Medical College Hospital & Research Institute, Rheumatology and Medicine, Madurai,
Rheumatology and Medicine, Madurai
madurai
India
625001

Sponsor information

Organisation
Cadila Healthcare Ltd.

ROR
https://ror.org/03ktyvw44

Funder(s)

Funder type
Industry

Funder Name
Cadila Healthcare Ltd.

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Karmic Lifesciences LLP (dhiraj.patel@karmiclifesciences.com). The data available will be output analyzed data and will be available from 1st March 2019 for 3 months.

Data is available for any analyses by written email request to be shared with only healthcare practitioners. Consent was obtained from participants and data is anonymised. The data is ethically approved and legal restriction for countries where approval for drug is not there.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results in patients with rheumatoid arthritis	01/09/2019	09/07/2019	Yes	No
Results article	results in patients with ankylosing spondylitis	12/08/2019	02/12/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes