NON-INTERVENTIONAL (NI) STUDY PROTOCOL

Study Information

Title	Efficacy of Etanercept in Iraqi Patients with Moderate to Severe Psoriasis: 5 Years Data from local registry.
Protocol number	B1801412
Protocol version identifier	3.0
Date	28 July 2021
Active substance	Etanercept
Medicinal product	Etanercept
Research question and objectives	This study aims to evaluate the efficacy of Enbrel as a biological treatment in moderate to severe plaque psoriasis patients in Iraq.
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2. LIST OF ABBREVIATIONS

Abbreviation	Definition
AE	Adverse Event
BSA	Body Surface Area
DLQI	Dermatology Life Quality Index
IEC	Independent Ethics Committee
IRB	Institutional Review Board
PASI	Psoriasis Area and Severity Index
SPSS	Statistical Package for the Social Science (Software)

3. RESPONSIBLE PARTIES

Principal Investigator(s) of the Protocol

Name, degree(s)	Job Title	Affiliation	Address
PPD MD, M.Sc.	Medical Advisor NI Study Lead	Pfizer Inc – Iraq	PPD

4. AMENDMENTS AND UPDATES

Amendment number	Date	Protocol section(s) changed	Summary of amendment(s)	Reason
1	23 July 2021	Throughout document	Spelling errors	Administrative
		Section 5 Milestones	Aligned dates with Study Report	Administrative
2	28 July 2021	Throughout document	Spelling errors	Administrative
		Section 5 Milestones	Align dates with Study Report	Administrative

5. MILESTONES

Milestone	Planned date
Start of data collection	01 September 2020
End of data collection	01 October 2020
Final study report	01 September 2021

6. RATIONALE AND BACKGROUND

Iraq has over 5 years of experience in using Enbrel as a treatment for psoriasis patients, starting in 2014 when the first psoriasis patients received the first dose of Enbrel. Dermatologists in Baghdad Teaching Hospital observed a positive response in patients with psoriasis using a biological treatment such as Enbrel, this observation discussed this during our medical to medical interaction. Local data indicates the value of adherence and efficacy to treatment with Enbrel in patients with moderate-to-severe plaque psoriasis after five years of use. This study aims to address the need for evaluating local and regional data of Enbrel use in Iraqi psoriasis patients, as there is no local published and limited regional data, currently. With the expected number of patients for this study, this would be the largest regional study for the evaluation of data on Enbrel use in Iraqi patients with moderate-to-severe psoriasis.

This study will evaluate local data available in Iraqi patients with moderate-to-severe psoriasis on Enbrel treatment with regards to efficacy, treatment-regimen adherence, and patient characterization (ie, age, gender, and smoking status).

7. RESEARCH QUESTION AND OBJECTIVES

This study aims to evaluate the efficacy of Enbrel as a biological treatment in moderate-to-severe plaque psoriasis patients in Iraq.

Primary objective: Efficacy of Enbrel in patients with moderate-to-severe plaque psoriasis by measuring baseline BSA, PASI, and DLQI scores compared to BSA, PASI, and DLQI scores after 6 months of initiation of treatment and compared to the last visit follow-up BSA, PASI, and DLQI scores.

Secondary objective:

Determine the first year adherence of patients with moderate-to-severe plaque psoriasis on a Enbrel treatment.

8. RESEARCH METHODS

8.1. Study Design

This is a retrospective analysis of approximately 400 Iraqi patients diagnosed with moderate-to-severe plaque psoriasis that received Enbrel as treatment for disease.

Baseline, 6 months after initiation of Enbrel treatment and last visit follow-up, BSA, PASI, and DLQI scores for identified patients will be collected and used to evaluate efficacy. Patients will be further divided into 2 groups according to their adherence to Enbrel treatment (The adherent group will include the patients who were adherent to Enbrel treatment for one and seven years, and the non-adherent group will include patients who did not adhere to Enbrel).There will then be a comparison between both groups; in BSA, PASI, and DLQI scores at baseline, 6-months after Enbrel treatment, and at last visit follow-up after Enbrel treatment.

Patient demographic information (eg, age gender, disease duration) will be analyzed throughout the study.

8.2. Setting

Patients ≥18 years of age will be identified from the local registry at the Dermatology Center in Baghdad Teaching Hospital. Patients diagnosed with moderate-to-severe plaque psoriasis and have been receiving Enbrel treatment for at least 1-year duration are eligible for inclusion in the study.

8.2.1. Inclusion Criteria

Patients must meet each of the following inclusion criteria to be eligible for inclusion in the study:

1. Confirmed diagnosis of moderate-to-severe plaque psoriasis and receiving etanercept treatment for a minimum duration of 1 year.

2. Age ≥18 years old.

3. No history of using a biological treatment, other than etanercept, for treatment of moderate to severe plaque psoriasis or any other reason.

8.2.2. Exclusion Criteria

Patients meeting any of the following criteria will not be included in the study:

1. Etanercept use for treatment moderate-to-severe plaque psoriasis less than 1-year duration.

2. Previous use of other biological treatments for any reason.

8.3. Data Sources

Data will be collected from the local registry at the Dermatology Center of Baghdad Teaching Hospital. The data are structured and will be analyzed by the investigator.

8.4. Study Size

This study will include approximately 400 patients from the local registry that meet the inclusion criteria detailed in that described previously.

8.5. Data Management

The structured data is exported into an Excel spreadsheet. It will then be transferred to the SPSS database (version 23) which will be used for data management and analysis.

8.6. Data Analysis

Categorical covariances will be described by frequency distribution while continuous covariates will be expressed in terms of their mean and standard deviation or median and interquartile range as appropriate. The unadjusted comparisons between groups of the covariates and the outcomes will be evaluated using chi-squared tests for categorical data, while for continuous data, the student's t-test for normally distributed variables and the Kruskall-Wallis test for non-parametric data will be used.

8.7. Quality Control

Not applicable.

8.8. Limitations of the Research Methods

Missing data that could lead to bias is an identified limitation in this study.

8.9. Other Aspects

Not applicable.

9. PROTECTION OF HUMAN SUBJECTS

9.1. Patient Information

This study involves data that exist in anonymized structured format and contain no patient personal information.

9.2. Patient Consent

As this study involves anonymized structured data, which according to applicable legal requirements do not contain data subject to privacy laws, obtaining informed consent from patients by Pfizer is not required.

9.3. Institutional Review Board (IRB)/Independent Ethics Committee (IEC)

There must be prospective approval of the study protocol, protocol amendments, and other relevant documents (eg, informed consent forms if applicable) from the relevant IRBs/IECs. All correspondence with the IRB/IEC must be retained. Copies of IRB/IEC approvals must be forwarded to Pfizer.

9.4. Ethical Conduct of the Study

The study conducted in accordance with legal and regulatory requirements, as well as, with scientific purpose, value, and rigor and follow generally accepted research practices described in Guidelines for Good Pharmacoepidemiology Practices (GPP) issued by the International Society for Pharmacoepidemiology (ISPE), Good Epidemiological Practice (GEP) guidelines issued by the International Epidemiological Association (IEA), and Good Practices for Outcomes Research issued by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR).

10. MANAGEMENT AND REPORTING OF ADVERSE EVENTS/ADVERSE REACTIONS

This study involves data that exist as structured data by the time of study start.

In these data sources, individual patient data are not retrieved or validated, and it is not possible to link (ie, identify a potential association between) a particular product and medical event for any individual. Thus, the *minimum criteria for reporting an adverse event (AE) (ie, identifiable patient, identifiable reporter, a suspect product, and event) cannot be met*.

11. PLANS FOR DISSEMINATING AND COMMUNICATING STUDY RESULTS

In the event of any prohibition or restriction imposed (eg, clinical hold) by any applicable competent authority in any area of the world, or if the investigator is aware of any new information that might influence the evaluation of the benefits and risks of a Pfizer product, Pfizer should be informed immediately.

12. REFERENCES

Not applicable.

13. LIST OF TABLES

Not applicable.

14. LIST OF FIGURES

Not applicable.

ANNEX 1. LIST OF STAND ALONE DOCUMENTS

None.

Document Approval Record

Document Name:	B1801412 Non Interventional Protocol Amendment 2 (clean) 28 July 2021
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Signed By:	Date(GMT)	Signing Capacity
PPD	05-Aug-2021 13:02:51	Author Approval