NON-INTERVENTIONAL (NI) STUDY PROTOCOL

Study Information

Title	The Impact of Difficult to Treat Sites on Biological Treatment Response in Patients with Moderate-to-Severe Plaque Psoriasis
Protocol number	B1801416
Protocol version identifier	Version 3.0
Date	27 July 2021
Active substance	Etanercept
Medicinal product	Etanercept
Research question and objectives	This study aims to evaluate the impact of difficult to treat sites on biological response in moderate-to-severe plaque psoriasis in Iraqi patients.
Author	PPD MD, M.Sc. PPD Pfizer – Iraq

1. TABLE OF CONTENTS

2. LIST OF ABBREVIATIONS

Abbreviation	Term
AE	Adverse Event
BSA	Body Surface Area
IEC	Independent Ethics Committee
IRB	Institutional Review Board

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. ABSTRACT

See Annex 1.

5. AMENDMENTS AND UPDATES

Amendment number	Date	Protocol section(s) changed	Summary of amendment(s)	Reason
1	28 May 2021	Section 8.5 Data Management Section 8.6 Data Analysis	Aligning with standard template	Administrative Administrative
2	10 June 2021	Section 4. Abstract Section 5. Milestones	Aligned with Study Report Aligned with Study Report	Administrative Administrative
3	27 July 2021	Throughout Document	Spelling errors	Administrative

6. MILESTONES

Milestone	Planned date	Actual Date
Start of data collection	20 July 2020	20 July 2020
End of data collection	01 August 2020	01 August 2020
Final study report	30 Jun 2021 2020	30 Jun 2021

7. RATIONALE AND BACKGROUND

Iraq has over 4 years of experience using Enbrel for treatment of plaque psoriasis (PsO) in patients but the first PsO patients to receive Enbrel was in 2014. The dermatologists at the Baghdad Teaching Hospital observed a positive response from patients on Enbrel and it was discussed during the medical to medical interaction. The difficult to treat sites (scalp, face, skin folds, palms/soles and nails) are a major obstacle in the treatment of PsO.[1] The biological treatment is indicated for moderate-to-severe plaque psoriasis patients with difficult to treat sites. Since there is no local published data and limited regional data regarding the use of Enbrel in Iraqi PsO patients with difficult to treat sites, this study is essential. 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 PsO.

8. RESEARCH QUESTION AND OBJECTIVES

This study aims to see the efficacy of Enbrel as a biological treatment for PsO in Iraqi patients who have difficult to treat sites at presentation.

Primary objective: Efficacy of Enbrel in plaque psoriasis with difficult to treat sites by measuring the following baselines: BSA, PASI and DLQI. A comparison between 6 months after treatment and last visit follow-up will be analyzed.

Secondary objective:

Determine the adherence of patients to the biological treatment.

9. RESEARCH METHODS

9.1. Study Design

This is a retrospective analysis of approximately 400 patients that were diagnosed with moderate-to-severe plaque psoriasis with difficult to treat sites. Patients will receive Enbrel as treatment for their disease and will include primary and secondary endpoints.

Primary objective: Efficacy of Enbrel in Moderate-to-Severe Plaque Psoriasis with difficult to treat sites by measuring the baselines of BSA, PASI and DLQI and compare it with 6 months after treatment and last visit follow-up during study.

Secondary objective:

- Determine the compliance of patients with Moderate-to-Severe Plaque Psoriasis on Enbrel.
- Will take the baselines of BSA, PASI and DLQI for 6 months after treatment and last visit disease activity index to see the efficacy.
- The patients will be divided into 2 groups according to their adherence to Enbrel. and will be compared between both groups in BSA, PASI and DLQI at 6 months after treatment and last visit disease activity index.

Also the demographic characterization of patients will be obtained (patients age, gender, disease duration, etc.) during data collection.

9.2. Setting

The study population will be obtained from a local registry, including patients diagnosed with moderate-to-severe plaque psoriasis and have been receiving etanercept treatment for at least 1-year. Study population must be ≥18 years of age and have difficult to treat sites at presentation.

9.2.1. Inclusion Criteria

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

1. Moderate-to-severe plaque psoriasis patients who have been receiving etanercept for at least 1-year duration.
2. Have difficult to treat sites at presentation.
3. Age ≥18 years.
4. No history of using other biological treatments, other than etanercept for the treatment of moderate-to-severe PsO.

9.2.2. Exclusion Criteria

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

1. Etanercept use for treatment of moderate-to-severe PsO less than 1-year duration.
2. Previous use of another biological treatment for treatment of moderate-to-severe PsO.

9.3. Data Sources

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

9.4. Study Size

This study will include approximately 400 patients from the registry that meet the inclusion criteria of having moderate-to-severe PsO with difficult to treat sites at presentation.

9.5. Data Management

Data already exists in a structured format and will be extracted to an excel spreadsheet which will be analyzed using the SPSS database (version 23).

9.6. Data Analysis

Detailed methodology for summary and statistical analyses of data collected in this study will be documented as below.

All covariates will be summarized to get information about frequency distribution and mean, median or standard deviation. Numbers and percentages will be provided for dichotomous and polychotomous variables when performing descriptive analysis of categorical data. Means, medians, standard deviations and interquartile range as appropriate will be provided for continuous variables when performing descriptive analysis of continuous data.

The bivariate analysis will be conducted to determine if there is any association between the outcome and the exposure (the covariates). Unadjusted comparisons of baseline characteristics for 0, 4, and 12 months after treatment and last visit disease activity index against outcome measures will be provided. Appropriate tests will be used based on the distribution of the measure: chi-square test will be used for categorical variables, t-test will be used for continuous variables, and the Kruskall-Wallis test for non-parametric variables; p-values will also be generated.

No regression model will be built for this analysis.

9.7. Quality Control

N/A.

9.8. Limitations of the Research Methods

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

10. OTHER ASPECTS

Not applicable.

11. PROTECTION OF HUMAN SUBJECTS

11.1. Patient Information

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

11.2. 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.

11.3. 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.

11.4. 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).

12. 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.

13. PLANS FOR DISSEMINATING AND COMMUNICATING STUDY RESULTS

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

14. REFERENCES

1. Kragballe, Knud. "Management of difficult to treat locations of psoriasis." *Management of Psoriasis*. Vol. 38. Karger Publishers, 2009. 160-171.

15. LIST OF TABLES

None.

16. LIST OF FIGURES

None.

ANNEX 1. LIST OF STAND-ALONE DOCUMENTS

Number	Document reference number	Date	Title
1	Section 4	15 June 2021	*The Impact of Difficult to Treat Sites on Biological Treatment Response in Patients with Moderate-to-Severe Plaque Psoriasis*

Document Approval Record

Document Name:	B1801416 Amendment 3 Non Interventional Protocol (clean) (PsO Difficult to Treat sites) 27 July 2021
Document Title:	B1801416 Amendment 3 Non Interventional Protocol (clean) (PsO Difficult to Treat sites) 27 July 2021

Signed By:	Date(GMT)	Signing Capacity
PPD	27-Jul-2021 15:18:03	Author Approval