

1.0 Abstract

Title

Special Investigation (Working Productivity and Activity Impairment in Japanese Patients with Psoriatic Arthritis)

Keywords

Adalimumab, Psoriatic Arthritis, WPAI

Rationale and Background

<Background>

In Japan, scientific evidence which shows improvement in WPAI-PsA with biologics is missing.

<Rationale>

Previous studies showed 1) significant work productivity and activity impairment in Japanese patients with psoriasis arthritis (PsA) compared to psoriasis without arthritis (M Hayashi et al. Journal of Dermatological Science. 72 (2013); 2) improvements in work productivity and activity impairment after 16 weeks of adalimumab treatment for patients with psoriasis (including 25% PsA) (Alex Boer Kimball et al. J Am Acad Dermatol. 2012); 3) improvements in PASI score and DAS28 (Humira[®] 40 mg for S.C. Injection - Study Protocol for Special Investigation in Patients with Ps and PsA (All-Case study) P12-077). Accordingly, improvement of disease activity scores and WPAI-PsA scores was expected in this study of patients with PsA.

Research Questions and Objectives

To assess the effectiveness of adalimumab on PsA-related overall work impairment (OWI).

Research Methods

Study Design

This was a single-arm, multicenter, prospective cohort study (post marketing observational study). The observation period was 24 weeks or discontinuation in this study.

Setting

This study was conducted from 15 December 2014 to 13 March 2017. This registration period of subjects was from 15 December 2014 to 30 September 2016.

Subjects and Study Size, Including Dropouts

[Subjects]

<Inclusion Criteria>

Patients who have never been administered adalimumab. PsA patients met diagnostic criteria for CASPAR criteria. They should be paid workers (including part-time workers).

<Exclusion Criteria>

Patients showing decreased basic activities of daily life, such as hospitalization or being bedridden. Patients with contraindications to adalimumab.

[Study size]

130 patients

Variables and Data Sources

[Variables]

Effectiveness

WPAI:PsA, PASE, PASI, DAS28, HAQ-DI, BASDAI

Safety

Adverse events, adverse drug reactions

[Data Sources]

Data sources in this study are from the institute's medical charts. Participant physicians in this study transcribed the data from medical charts to case report forms (CRF) which AbbVie prepared.

Results

This investigation was conducted from December, 2014 to March, 2017 as a postmarketing observational study of Humira. The number of patients in the safety analysis set was 148, and the number of patients in the efficacy analysis set was 106. Also note that patients under 18-year-old were not included in this investigation.

[Effectiveness]

OWI score in 106 patients in the efficacy analysis set was 40.22 ± 32.84 at baselines. A change in the score in 70 patients was -16.35 ± 24.35 at 4 weeks after the start of treatment, thus, a statistically significant difference was observed. The score improved subsequently, and the change in the score in 79 patients was -25.24 ± 35.27 at 24 weeks after the start of treatment.

PASE score in 106 patients in the efficacy analysis set was 47.4 ± 11.7 at baselines. A change in the score in 74 patients was -11.8 ± 11.0 at 4 weeks after the start of

treatment, thus, a statistically significant difference was observed. The score improved subsequently, and the change in the score in 83 patients was -18.1 ± 14.0 at 24 weeks after the start of treatment.

[Safety]

Thirty nine adverse events were observed in 32 patients in 148 patients in the safety analysis set, and the incidence rate of adverse events was 21.62% (32/148).

Thirty three adverse drug reactions were observed in 28 patients out of 148 patients in the safety analysis set, and the incidence rate of adverse drug reactions was 18.92%(28/148). Three serious adverse drug reactions were observed in 3 patients out of 148 patients, and the incidence rate of adverse drug reactions was 2.03% (3/148). The serious adverse drug reactions that had developed were one each of "cellulitis staphylococcal", "lupus nephritis", and "paradoxical drug reaction "

Discussion

Statistically significant differences were observed in the change of WPAI:PsA throughout the entire assessment period from 4 weeks to 24 weeks after the start of treatment in any of the questions such as "percent work time missed due to psoriatic arthritis", "percent impairment while working due to psoriatic arthritis", "percent overall work impairment due to psoriatic arthritis" and "percent activity impairment due to psoriatic arthritis".

In safety, frequency of incident of adverse drug reactions and factors that affect incident of adverse drug reactions were similar to what was found in special drug use survey of Humira (P12-077) and some difference was observed in the safety profile.

Adalimumab provided an improvement of work productivity and activity impairment for psoriatic arthritis in Japanese patients during the 24 weeks of treatment as well as the effectiveness evaluation measures such as PASE, DAS28, TJC, SJC, PASI, HAQ-DI and BASDAI. Moreover this result suggested the possibility that

adalimumab prevent the labor failure due to PsA. Safety was consistent with the known and described safety profile of adalimumab.

Marketing Authorization Holder(s)

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Names and Affiliations of Principal Investigators

Not applicable.