

1.0 Abstract

Title

Effectiveness of Adalimumab (HUMIRA®) in the Treatment of Scalp and Nail Affection in Patients with Moderate to Severe Plaque Psoriasis in Routine Clinical Practice

Keywords

Adalimumab, Humira®, Plaque Psoriasis, Scalp Psoriasis, Nail Psoriasis, PMOS

Rationale and Background

The clinical efficacy and safety of the recombinant, fully human, IgG1 monoclonal antibody Adalimumab (Humira®) in patients with moderate to severe chronic plaque psoriasis have been demonstrated in several randomized, double-blind, controlled clinical trials.

However, there are no published data yet from non-interventional studies reflecting the effectiveness of biologic agents in routine clinical practice. The aim of this PMOS was therefore to evaluate the long-term effectiveness of adalimumab (Humira®) in the treatment of nail and scalp psoriatic lesions in routine dermatologic practice.

Research Question and Objectives

The primary objective of this PMOS was to evaluate the improvement of scalp and nail psoriasis in patients with moderate to severe plaque psoriasis after treatment with adalimumab (Humira®).

Secondary objectives included the evaluation of general improvement of psoriasis, assessment of quality of life and the association between general, nail or scalp improvement and quality of life.

Study Design

This prospective post-marketing observational study (PMOS) was performed in a multicenter, multi-country and single-arm design.

Setting

Participating countries were Slovenia, Hungary, Slovakia, Romania, Israel, Czech Republic, Ukraine and Estonia.

Subjects and Study Size, Including Dropouts

For 506 patients a V0 visit has been documented. However, 5 patients were lost to follow-up after the baseline visit and had no further entries regarding treatment with adalimumab (Humira®). These patients were excluded from the full analysis set (FAS) which finally comprises 501 patients. From these 157 patients were included in the nail psoriasis set (NPS) and 404 patients in the scalp psoriasis set (SPS) with an overlap of 119 patients who were included in both, the NPS and the SPS. 13.4% of the patients discontinued treatment with adalimumab (Humira®) during the study.

Variables and Data Sources

For the analysis of the study objectives the Nail Psoriasis Severity Index (NAPSI), the Psoriasis Scalp Severity Index (PSSI), the Psoriasis Area and Severity Index (PASI) and the Dermatology Life Quality Index (DLQI) were applied.

Results

84.0% of the patients in the NPS and even 93.8% in the SPS achieved clinical response by treatment with adalimumab (Humira®) at the end of the study. There was also a clear improvement in general psoriasis and in the quality of life. A moderate to strong association between general, nail or scalp improvement and quality of life could be seen. Adalimumab (Humira®) showed a high tolerability with only 9.6% of the patients having an adverse event and 6.0% an adverse drug reaction during the course of the study.

Discussion

Use of adalimumab (Humira®) appears to be a potent and well-tolerated treatment of scalp and nail psoriasis in patients with moderate to severe plaque psoriasis. This observational study provides the rationale for further randomized clinical trials in the quest for an improved treatment regimen in patients with nail and scalp psoriasis.

Marketing Authorisation Holder

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Names and Affiliations of Principal Investigators

[REDACTED]

redacted information 14Nov2014