# Etanercept in dermatological practice – authors' own experience in the treatment of psoriasis vulgaris and psoriatic arthritis

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## Abstract

**Introduction:** The important role of TNF-$\alpha$, a proinflammatory cytokine, in the pathogenesis of psoriasis vulgaris and psoriatic arthritis justifies the use of therapy with etanercept, which has proved to be effective in the treatment of skin lesions and joint problems.
**Aim:** The paper presents the authors' own experience in evaluation of the efficacy and safety of etanercept in the treatment of psoriasis vulgaris and psoriatic arthritis in adults and in children.
**Conclusions:** According to the authors' observations, etanercept administered in the dose of 50 mg once a week was characterized by patients' high tolerance and by induction of significant skin condition improvement in patients with psoriasis vulgaris and reduction of joint complaints in patients with psoriatic arthritis, with concomitant improvement of patients' quality of life.

**Key words:** etanercept, tumour necrosis factor $\alpha$, psoriatic arthritis, Psoriasis Area and Severity Index.

## Introduction

Psoriasis is a chronic, inflammatory skin disorder with systemic consequences, which affects about 2% of the population [1]. The main subtypes of psoriasis include plaque psoriasis (the most common form; 80-90%), pustular psoriasis and erythrodermic psoriasis.

Recent years have brought special attention to the association of psoriasis with cardiovascular disease, diabetes mellitus, hypertension, obesity, inflammatory bowel disease, cancer and depression [2, 3]. It has also been found that general mortality among patients with severe psoriasis has increased [4].

Psoriatic arthritis (PsA) is an inflammatory, seronegative spondyloarthropathy associated with the occurrence of psoriasis vulgaris [2]. The incidence of PsA in patients suffering from psoriasis is the subject of controversy and is estimated to range from 6% to 42% depending on the studied population and accepted diagnostic criteria [5-8]. Psoriatic skin lesions in 80% of cases precede joint symptoms [9] and they are followed by the beginning of PsA after an average of 12 years [2]. Nearly 90% of psoriatic patients also present nail changes [10]. The clinical picture of PsA may be extremely heterogeneous: from involvement of one joint with mild course, to severe, erosive and distorting polyarthritis with poor prognosis in about 20% of patients [2, 11].

Elevated levels of TNF-$\alpha$ were found within psoriatic skin lesions [12] as well as within synovial fluid [13]. The role of this proinflammatory cytokine in the pathogenesis of psoriasis vulgaris and PsA has been confirmed in experimental models, and also therapy directed against TNF-$\alpha$ has proved to be effective in the treatment of skin lesions and joint problems [14].

Etanercept's mechanism of action involves competitive inhibition of TNF binding to its surface receptors (TNF-R), in consequence preventing a cellular, TNF-dependent response, and resulting in TNF inactivation. Etanercept may also modulate responses biologically controlled by other immunological molecules (i.e. cytokines, adhesive molecules, proteinases), which are induced or regulated by TNF [15]. The use of etanercept in dermatological practice includes psoriasis vulgaris (plaque psoriasis) and PsA. Etanercept is so far the only registered biological drug in the treatment of psoriasis vulgaris (plaque psoriasis) in children and adolescents over 8 years of age [15] (Table 1).

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## Aim

The aim of the work was to evaluate efficacy and safety of etanercept in the treatment of psoriasis vulgaris and PsA in adults and in children.

## Material and methods

The group of patients treated with the biological drug etanercept in the dermatological ward of the Provincial Hospital in Poznań from January 2009 to March 2011 consisted of 21 patients (13 male patients and 8 female patients). The mean age of patients was 46.6 years (range 16-68), including one patient who was not an adult and started the treatment at the age of 16 years (Tables 2, 3 A and 3 B).

Biological treatment was implemented on the basis of patients' earlier classification including disease history, physical examination, the panel of diagnostic laboratory tests and specialist's consultations. Patients with the presence of infectious factors, such as HIV, HBV, HCV, and *Mycobacterium tuberculosis* (based on chest X-ray and QuantiFERON-TBGold), were excluded.

**Table 1.** Characteristics of etanercept (Enbrel®)

| | |
|---|---|
| **Name of the drug** | Etanercept |
| **Drug structure** | Fusion protein of p75 TNF-receptor and Fc IgG1 |
| **Mechanism of action** | Inactivation of soluble TNF |
| **Dosage and route of administration** | 1 × 50 mg per week subcutaneously |
| **Indications** | Psoriasis vulgaris, PsA, psoriasis vulgaris in children and adolescents (over 8 years of age) |

Qualification of patients to the treatment included an evaluation of the severity of skin lesions assessed as medium and severe (PASI > 10 and BSA > 10%), as well as a significant reduction in the patient's quality of life, psychosocial functioning due to psoriasis (DLQI > 10), ineffectiveness or intolerance of traditional systemic agents (PUVA, methotrexate, cyclosporine A, retinoids) and activity of peripheral joint inflammation (Table 4).

In the study group 6 patients were diagnosed with psoriasis vulgaris, and 15 with PsA, preceded by a long history of psoriasis vulgaris. The duration of psoriasis vulgaris was 6-58 years (mean 22 years), and PSA 1-12 years (mean 5.7 years).

Etanercept was administered at a dose of 50 mg once weekly as a subcutaneous injection.

**Table 2.** Clinical data of patients before treatment with etanercept

| | |
|---|---|
| **Number of patients** | 21 |
| **Mean age [years], age range** | 46.6, 16-68 |
| **Psoriatic arthritis [%]** | 71.4 |
| **Mean duration of psoriasis vulgaris [years]** | 22 |
| **Mean duration of psoriatic arthritis [years]** | 5.7 |
| **PASI** | 16.6 |
| **BSA%** | 21.3 |
| **DLQI** | 11.8 |
| **Treatment of psoriasis according to history [%]** | |
| Classical systemic therapy (MTX, CsA, retinoids, PUVA) | 19 (90.5%) |
| Biological therapy | 3 (14.3%) |

**Table 3 A.** Characteristics of patients treated currently

| *N* | Gender | Age [years] | Ps [years] | PsA [years] | PASI | PASI after 4 weeks | PASI after 12 weeks | PASI after 24 weeks | BSA | BSA after 12 weeks | DLQI | DLQI after 12 weeks |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | M | 47 | 25 | 2 | 10.2 | 6.7 | 1.8 | 0 | 32 | 6 | 11 | 1 |
| 2 | F | 45 | 35 | 12 | 10.1 | 6 | 6.6 | 9.8 | 17 | 13 | 14 | 5 |
| 3* | F | 46 | 25 | 10 | 11.3 | 8 | 4.8 | 1.5 | 11 | 4 | 4 | 0 |
| 4* | M | 49 | 20 | 10 | 1.5 | 1 | 0 | 0 | 4 | 0 | 0 | 0 |
| 5 | M | 58 | 30 | 10 | 11.7 | 1.6 | 0.9 | 0.4 | 19 | 3 | 13 | 5 |
| 6 | M | 57 | 16 | 4 | 16.8 | 9.1 | 5.6 | 4.6 | 29 | 11 | 10 | 4 |
| 7 | F | 59 | 20 | 2 | 24 | 14.1 | 5.7 | 4.8 | 57 | 35 | 17 | 5 |
| 8 | F | 50 | 10 | 8 | 5 | 6.8 | 4.9 | – | 14 | 11 | 8 | 4 |
| 9* | F | 51 | 32 | 1 | 11.5 | – | – | – | 13 | – | 11 | – |
| 10 | M | 66 | 30 | 2 | 18.2 | 8.7 | – | – | 17 | – | 30 | – |

**A history of biological drug infliximab therapy (discontinued due to lack of drug reimbursement)*

**Table 3 B.** Characteristics of patients treated from January 2009 to 2010

| *N* | Gender | Age [years] | Ps [years] | PsA [years] | PASI | PASI after 4 weeks | PASI after 12 weeks |
|---|---|---|---|---|---|---|---|
| 1 | M | 40 | 30 | – | 10.8 | 2.6 | 0 |
| 2 | M | 45 | 8 | 4 | 6.6 | 4.2 | 2.1 |
| 3 | M | 24 | 6 | 2 | 10.8 | 4 | 0 |
| 4 | F | 26 | 15 | – | 11.5 | 3.5 | 0.9 |
| 5 | M | 66 | 20 | – | 18.5 | 8.3 | 0 |
| 6* | M | 16 | 13 | – | 18.3 | 10.6 | 6.6 |
| 7 | F | 52 | 10 | 3 | 35.6 | 16.4 | 8.5 |
| 8 | F | 68 | 58 | – | 18.9 | 16.5 | – |
| 9 | M | 46 | 31 | 10 | 30.4 | 14.9 | – |
| 10 | M | 30 | 10 | – | 31.2 | 8.3 | 6.2 |
| 11 | M | 38 | 18 | 5 | 39.5 | 15.4 | – |

**Patient excluded from treatment and follow-up due to the sudden appearance of skin psoriatic lesions, which was interpreted as the lack of therapeutic effect*

## Results

In the group of analysed patients, etanercept was characterized by a good or very good therapeutic effect.

### Drug efficacy

The assessment of PASI at week 12 was possible in 16 out of 21 patients, since 3 of them for personal reasons finished the treatment before that time, and two patients used the drug for less than 12 weeks. In three cases after week 12 the therapy was abandoned because of exacerbation of skin lesions. Also one patient discontinued the treatment after week 12 for personal reasons.

In 21 patients the mean PASI value before treatment with etanercept was 16.8. After 4 weeks of treatment the mean PASI value was 8.3 and after 12 weeks of therapy was 3.4.

PASI75 at week 12 of therapy was achieved in 10 patients, including complete or almost complete elimination of skin lesions observed in 6 individuals. In the examined group 4 patients achieved PASI50 at week 12 of therapy.

Currently in the dermatological ward of the Provincial Hospital in Poznań etanercept therapy is conducted on 10 patients suffering from PsA. Mean PASI value at week 24 of the therapy was 3.0, although the evaluation was possible in 7 patients, because in 3 subjects the drug has been administered for a shorter time (Table 3 A).

In the presented group of patients (measured on 10 subjects) the resolution of psoriatic skin lesions was obtained (expressed as % of total body surface area) from 21.3% to 10.4%.

Clinical improvement was also observed in relation to inflammation of peripheral joints. Criteria for response to treatment of PsA (PsARC) at week 12 were reached in 93.3% of patients, including one patient treated for less than 12 weeks. More rapid reduction of joint symptoms was observed, such as reduction of swelling, tenderness and pain, in comparison to skin lesions. According to our

**Table 4.** Diagnostic tools

| | |
|---|---|
| **PASI** (***Psoriasis Area and Severity Index***) | Psoriasis severity index: 0 (no lesions) – 72 (severe lesions involving 100% of the body) |
| **BSA%** (***Body Surface Area %)*** | % of body area involved |
| **DLQI** (***Dermatology Life Quality Index***) | Questionnaire on impact of the skin disorder on the quality life (0-30 points, DLQI > 10 is a significant reduction in quality of life) |
| **PsARC** (***Psoriatic Arthritis Response Criteria***) | Response criteria to the treatment of PsA (2 of 4 required, including 1 or 2):<br>1) at least 30% improvement in tender joint counts<br>2) at least 30% improvement in swollen joint counts<br>3) an improvement of at least 1 unit (0-5 Likert scale) on the physician global assessment<br>4) an improvement of at least 1 unit (0-5 Likert scale) on the patient global assessment |

**Table 5.** Side effects

| Side effects | Number of patients (%) |
|---|---|
| Upper respiratory tract infections | 4 (19%) |
| Gain of body weight | 3 (14.3%) |
| Reaction at the injection site (erythema) | 2 (9.5%) |

observations of patients with PsA using 50 mg etanercept once a week, the effect of the drug on joint symptoms preceded the improvement of skin lesions for 1-2 weeks.

Significant improvement in patient quality of life (assessed in 10 subjects) measured with the use of DLQ1 was obtained – from mean 11.8 points to 3.0 points.

### Drug safety

In the analysed group of patients there were no serious adverse events observed during 24 weeks of treatment with etanercept. During the therapy monitoring, there were no serious abnormalities in physical examination or laboratory tests. Four patients reported upper respiratory tract infections. One patient required oral antibiotic treatment. Increase in body weight occurred in 3 patients. Reaction in the injection site was observed in 2 patients (Table 5).

## Discussion

The results of our observations do not differ significantly from earlier reports of other authors concerning etanercept therapy outcomes in patients with psoriasis and PsA. Due to the small number of patients, a comparison of the results to the multicentre clinical trials [16-20] should be treated with caution. Because most patients in our group (including 10 individuals currently receiving etanercept) suffer from PsA, we present selected studies with particular attention to this disease.

In the Mease study conducted on 30 patients with psoriasis and concomitant PsA, 87% of patients reached the PsARC criteria at 12 weeks of therapy, and PASI75 – 26% [21]. The PsARC result is comparable with our observation and confirms the effectiveness of etanercept in reducing joint symptoms. In another Mease analysis, the impact of etanercept on the radiographic image of PsA was assessed and demonstrated that etanercept significantly not only reduces the clinical symptoms, but also inhibits radiographic progression in comparison to the placebo group [22].

The EDUCATE study included a representative group of 1121 patients with PsA treated with etanercept in dermatological practice. Similarly to our group of patients, the primary reason for biological treatment inclusion was skin lesions. Dermatological aspects (including BSA, the severity of skin lesions in physician's assessment) and rheumatological aspects (such as evaluation of joint pain, morning stiffness, severity of disease in patient assessment) were evaluated before and during the course of biological therapy.

In 24 weeks of analysis, more than 50% of respondents achieved the status defined as "clear" or "almost clear" in relation to skin lesions, which is comparable to the PASI75 response. Sixty-eight percent improvement in the average number of painful joints and 70% improvement in the average number of swollen joints was observed [23]. The clinical improvement expressed as % of involved skin surface from 26.8% to 14.9% was obtained at week 12 of treatment, similar to our observations.

In the PRESTA study performed on 752 patients with psoriasis vulgaris and PsA the effectiveness of two dosing regimens of etanercept during the first 12 weeks of therapy was compared. At week 12 of therapy PASI75 was achieved in 36% of respondents at a dose of 50 mg 1 × week vs. 55% at a dose of 50 mg 2 × week, but there was no significant difference in the number of patients who fulfilled PsARC criteria (76.6% vs. 77%) [24]. The results show that intensification of initial etanercept treatment is associated with a faster response in relation to skin lesions, with no significant effect on the rate of joint symptom regression.

Our accepted regimen of 50 mg of etanercept once a week helped to achieve PASI75 at week 12 in 10 patients and appears to be optimal for most patients. In regards of the PRESTA study initiating a dose of 50 mg 2 × per week probably allows faster control of skin lesions in patients with severe skin manifestations of psoriasis. The higher PsARC results (93.3%) obtained by us presumably are associated with inclusion in the PRESTA study only of patients who met certain criteria defined by the authors.

The study conducted on 32 patients with active and progressive PsA treated continuously in a 3-year period showed high tolerance of etanercept therapy. No serious adverse reactions were observed and none of the respondents required discontinuation of treatment [25].

A separate discussion is required in the case of a 16-year-old patient with psoriasis vulgaris, in whom administration of etanercept was discontinued at week 16 due to lack of therapeutic effect. Clinical observation in week 4 of treatment seemed to be promising, but in the further course of therapy, due to eruption of new skin lesions, the patient's skin condition deteriorated. However the experience of Paller in the treatment of plaque psoriasis in a group of 211 younger patients (from 4 to 17 years of age) indicates a high efficacy and good tolerability of etanercept [26]. Therapy was continued in 181 patients who reached PASI50 after 12 weeks. In the 96-week long study, PASI50/75/90 was achieved respectively in 89%/61%/30% of patients, which demonstrates the efficacy of etanercept also in children [27].

A group of patients treated with etanercept with a similar quantity ($n$ = 20), but with lower incidence of PsA (30%) was observed at the Department of Dermatology, Medical University of Łódź [28]. After 12 weeks of therapy, improvement of skin (PASI50 and more) was detected in 4 of 15 observed patients. Adverse reactions were in most patients mild: reaction in the injection site, flu-like symptoms, headaches, herpes simplex infection. In 2 patients severe side effects were observed: optic neu-

ritis (discontinuation) and thrombocytopenia (after haematological consultation treatment was continued).

Reports of the effectiveness of biological therapies, including etanercept, in the treatment of nail psoriasis [29, 30], were also confirmed in our study patients (Figures 1, 2). Our own two-year experience in the use of etanercept provides us with evidence that for patients with psoriasis vulgaris and associated PsA, the drug is effective, with a high safety profile and also long-term therapy is possible.

Case reports of patients who achieved significant skin improvement and even complete remission of psoriatic

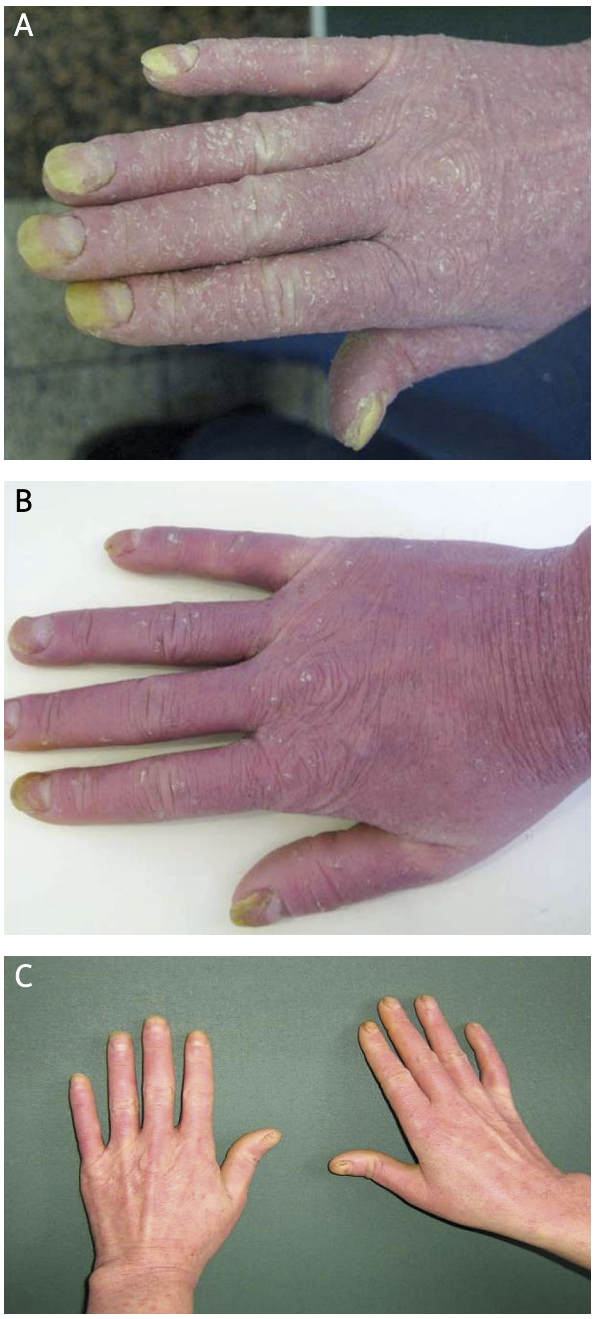


**Fig. 1.** Patient, 46 years old. **A** – Psoriatic lesions of the hands and fingernails before the therapy with etanercept. **B** – Improvement of psoriatic lesions of the hands and fingernails after 4 weeks of therapy with etanercept. **C** – Improvement of psoriatic lesions within hands and fingernails after 2 months of treatment

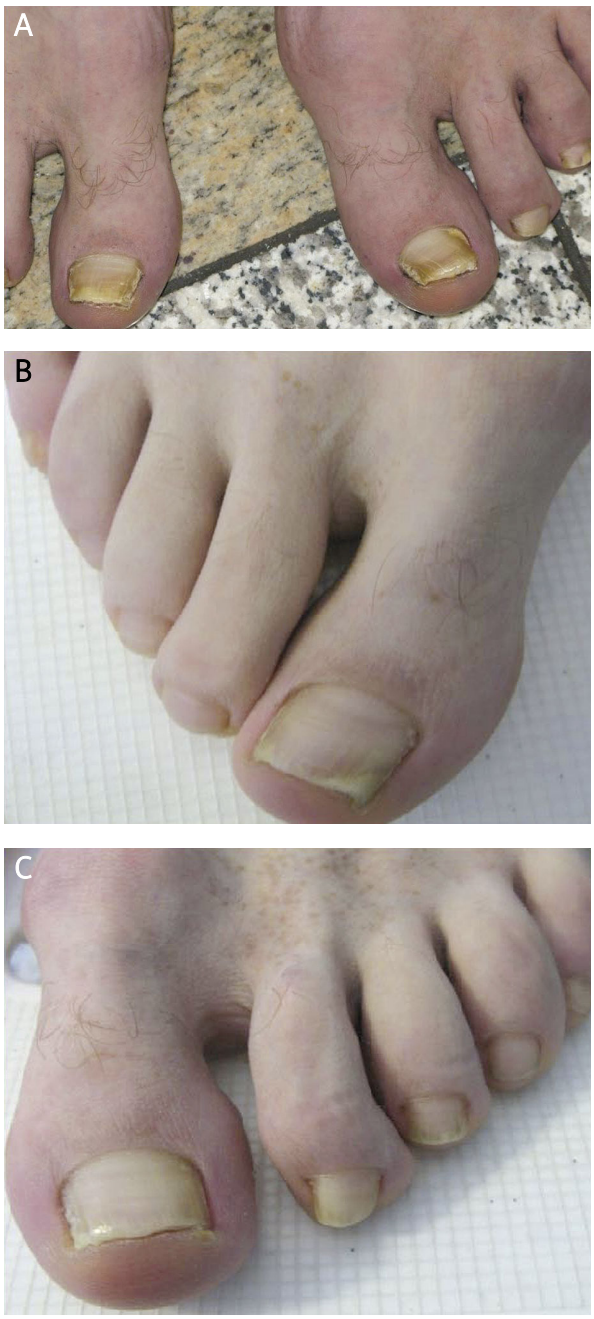


**Fig. 2.** Patient, 24 years old. **A** – Psoriatic lesions of toenails before treatment. **B** – Clinical improvement of psoriatic lesions within toenails after 12 weeks of treatment with the use of etanercept. **C** – Clinical improvement of psoriatic lesions within toenails after 12 weeks of treatment with the use of etanercept

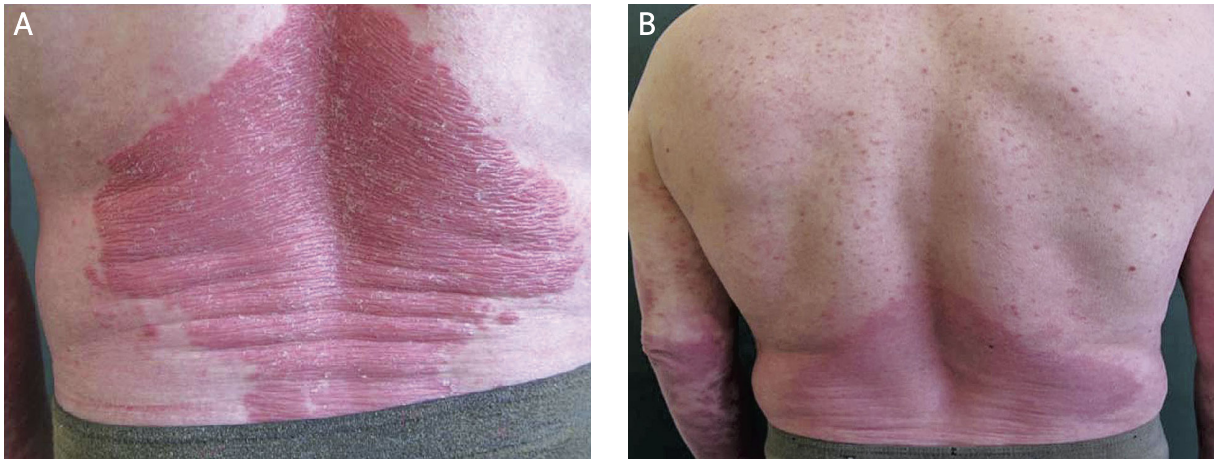


**Fig. 3.** Patient, 45 years old. **A** – Psoriatic lesions of the back before etanercept therapy. **B** – Alleviation of skin symptoms after 4 weeks of treatment with the use of etanercept

skin lesions after etanercept therapy are not uncommon. The great advantage of etanercept is its effectiveness in relation to the joint symptoms such as pain, tenderness and swelling, and possibly inhibition of the progress of PsA [22].

Early diagnosis and treatment implementation is essential to prevent the destruction and deformation of joints in the aggressive course of disease with an irreversible effect, impairing the personal and social life of patients.

We hope that further clinical studies will answer the question whether the long-term use of TNF-$\alpha$ inhibitors, including etanercept, affects the incidence of PsA in patients with psoriasis vulgaris; and whether through biological treatment of psoriasis vulgaris the development of PsA can be blocked or delayed [31].

## Conclusions

1. Etanercept administered in the dose of 50 mg once a week is a therapy characterized by patient high tolerance and by induction of significant skin condition improvement in patients with psoriasis vulgaris and reduction of joint complaints in patients with PsA, thereby improving the quality of patients' lives.
2. High long-term efficacy and tolerability of etanercept justifies its use in patients suffering from psoriasis, particularly in patients suffering from PsA.

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