

**Włodzimierz Samborski<sup>1</sup> and Przemysław Lisinski<sup>2</sup>**

# **Efficacy and Safety of Rheumafort in OA patients**

**<sup>1</sup>Department of Physiotherapy and Rheumatology,  
Poznan School of Medicine**

**<sup>2</sup>Department of Rehabilitation, Hospital no. 4 in Poznan**

# Study design

- **Rheumafort** versus **Placebo**
- According to OARSI\* criteria
- 6 weeks
- 60 patients with OA
  - Placebo controlled
  - Randomized
  - Parallel groups
  - Double blind

\*Osteoarthritis Research Society International

# Patients

- ❑ 58 men and women; age 26 - 78
- ❑ Diagnosed osteoarthritis stage II, II/III, and III according to X-ray

## Study protocol

- ❑ Visit –1 week: screening, washout period
- ❑ Visit 0 – start of study
- ❑ Visit +3 weeks – 1st follow-up visit
- ❑ Visit +6 weeks – 2nd follow-up visit, end of study

# How do we measure pain?

Pain is very **subjective**

International Measurement Standard

VAS - Visual Analog Scale



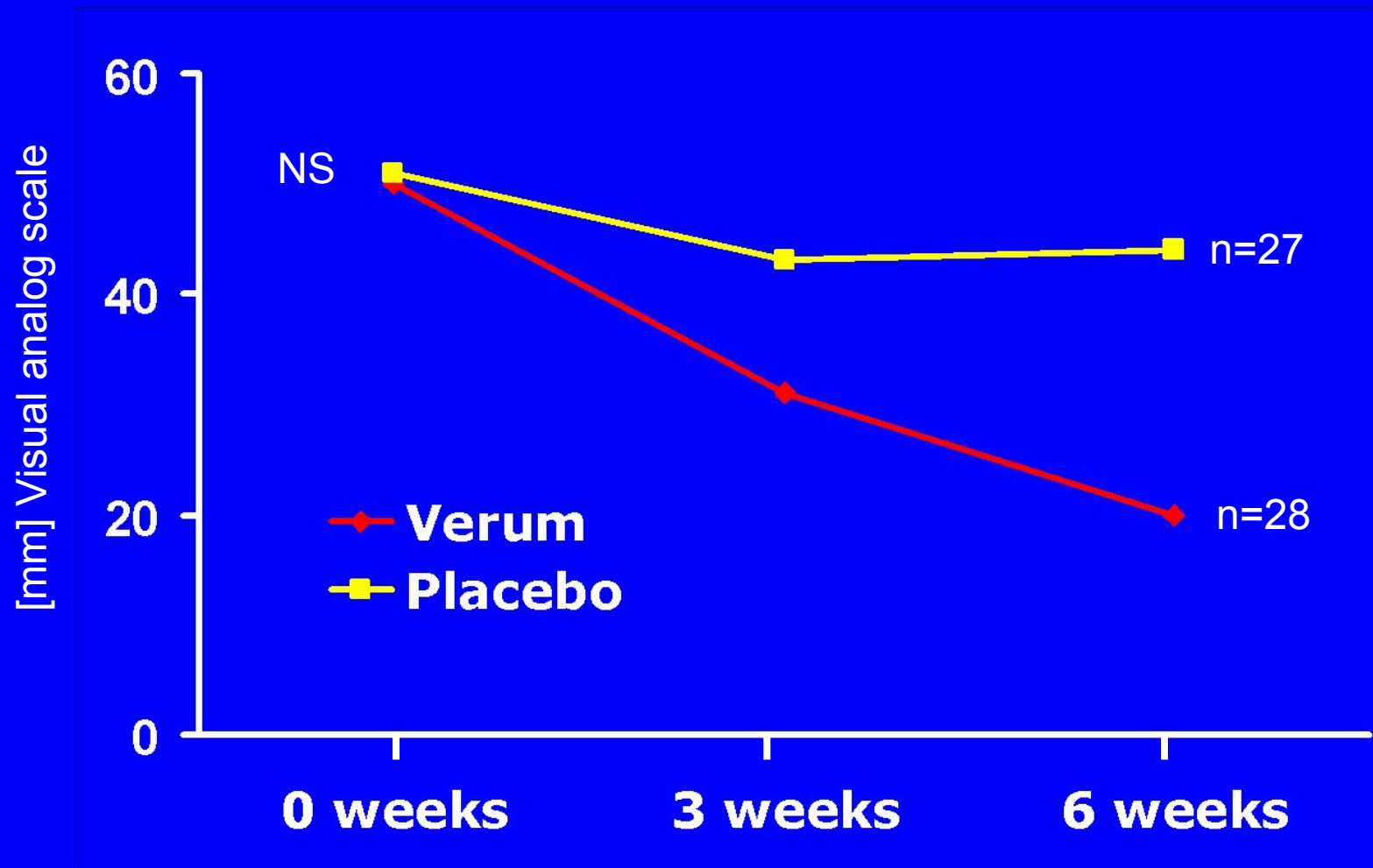
# **Rheumafort has been tested according to the strictest research criteria**

*How do we know if a product has a clinical relevant effect on joint pain and joint stiffness?*

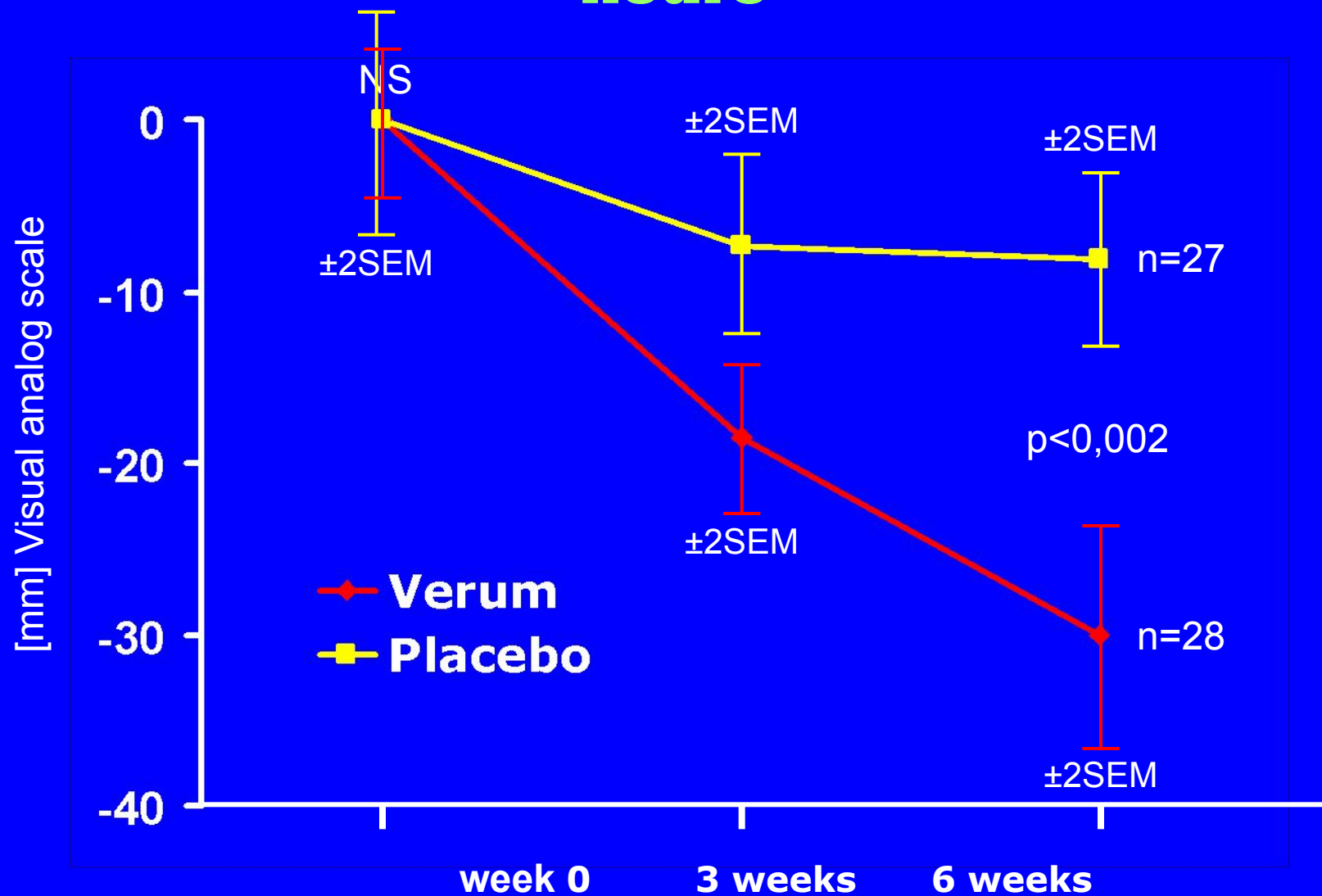
Patient must have a **minimum 15 mm improvement on the VAS-scale**

**= clinically relevant improvement**

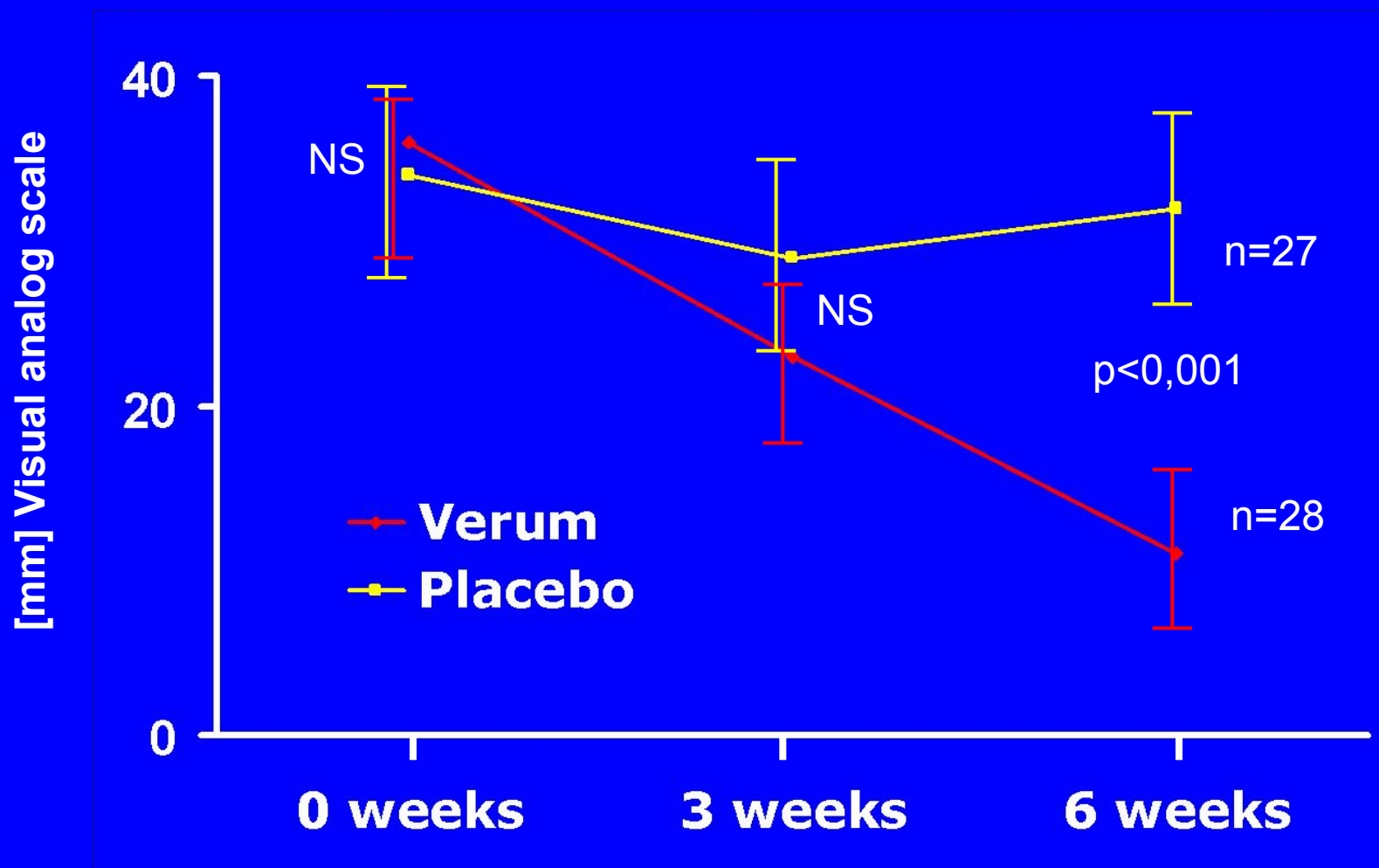
# Joint pain within last 24 hours



# Reduction of joint pain within last 24 hours

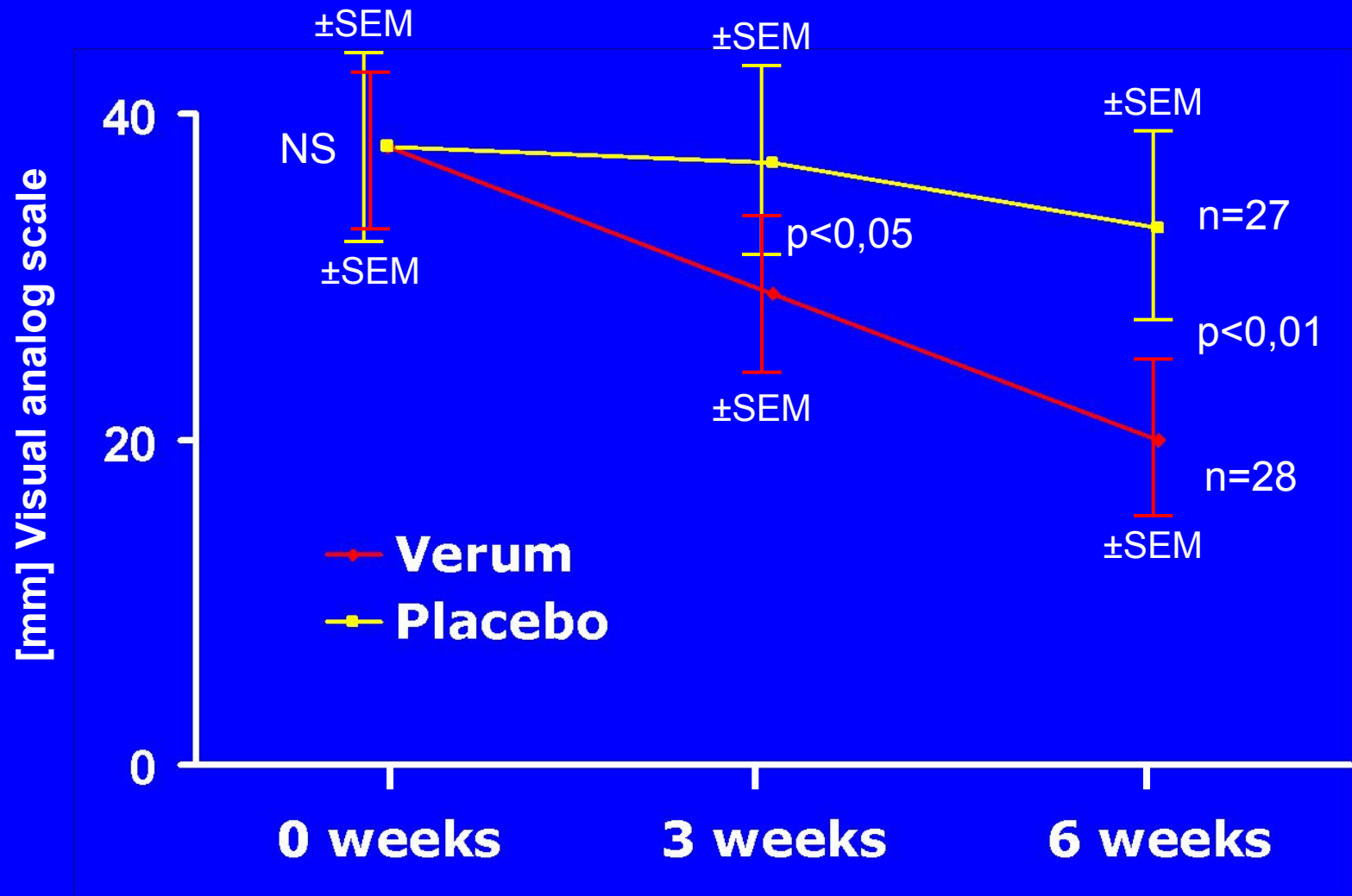


# Pain after 15 meter walk



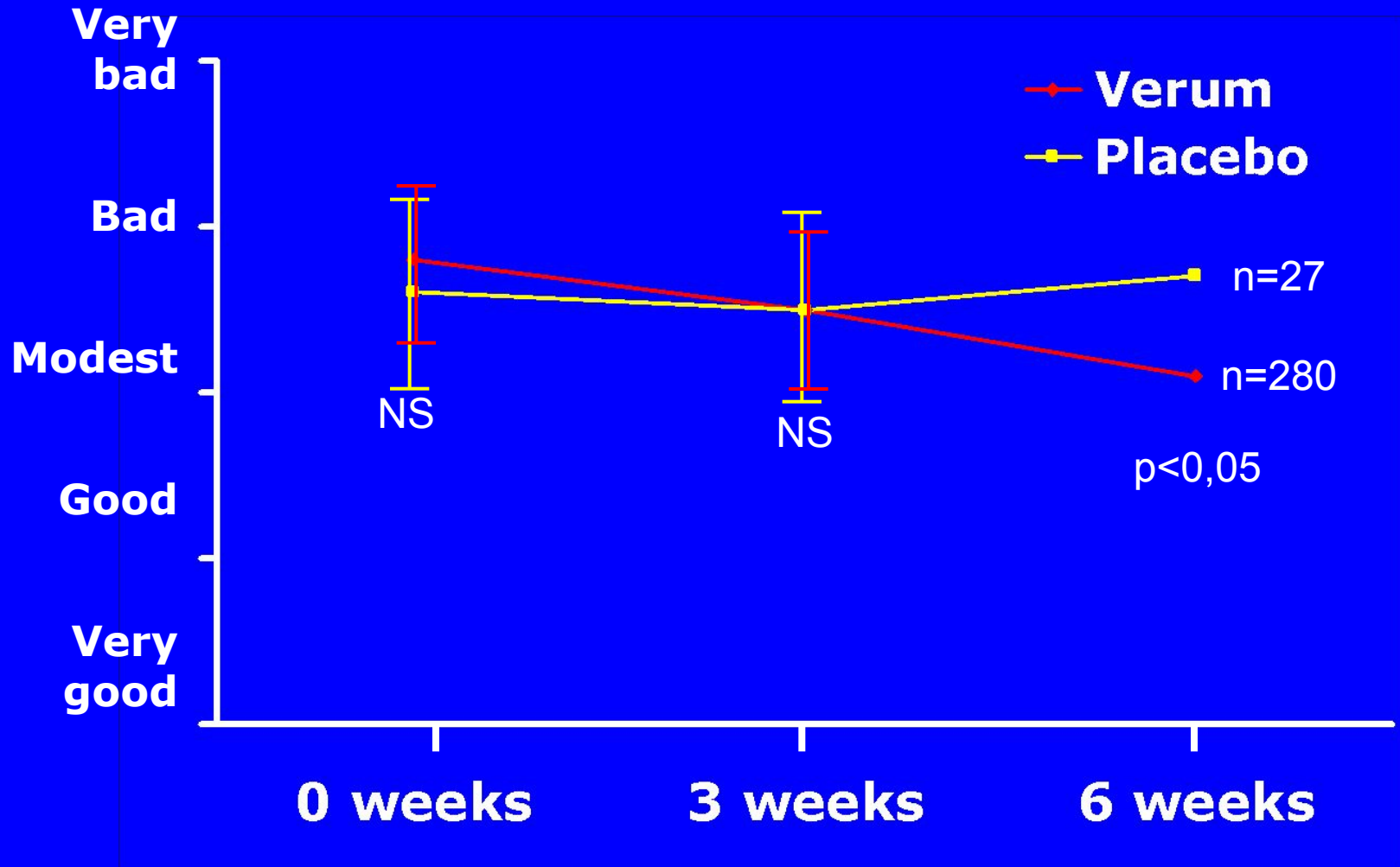


# Changes in WOMAC index

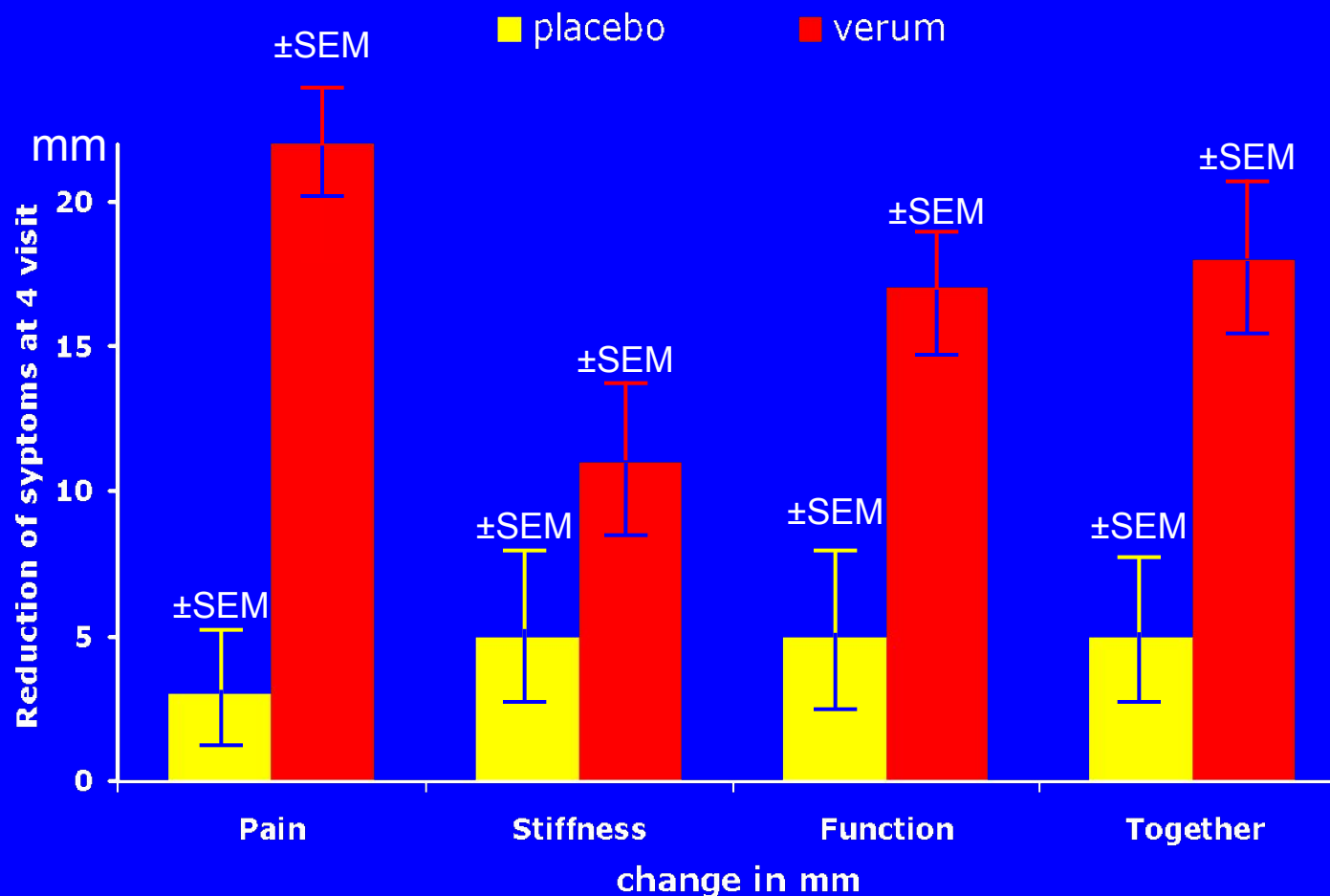


# Changes in well being

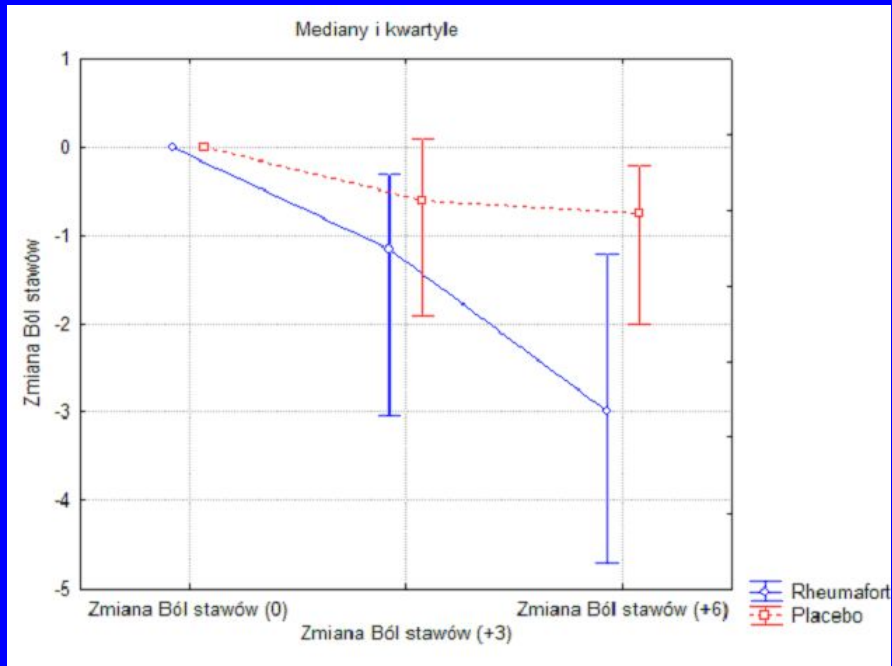
Likert scale



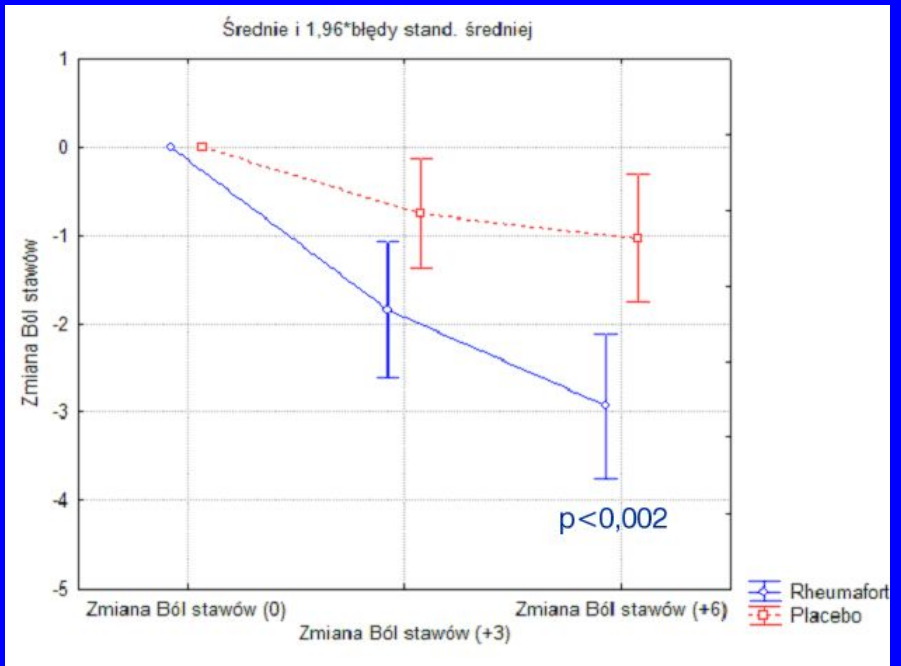
# WOMAC symptoms reduction after 6 weeks



# Reduction in joint pain within 24 hrs

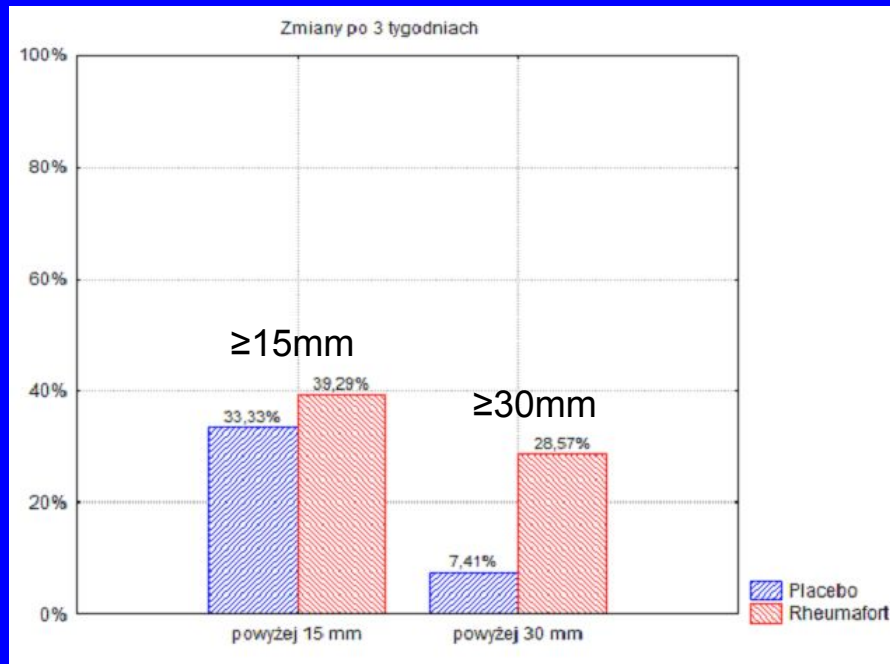


Median  $\pm$  quartile 2,3

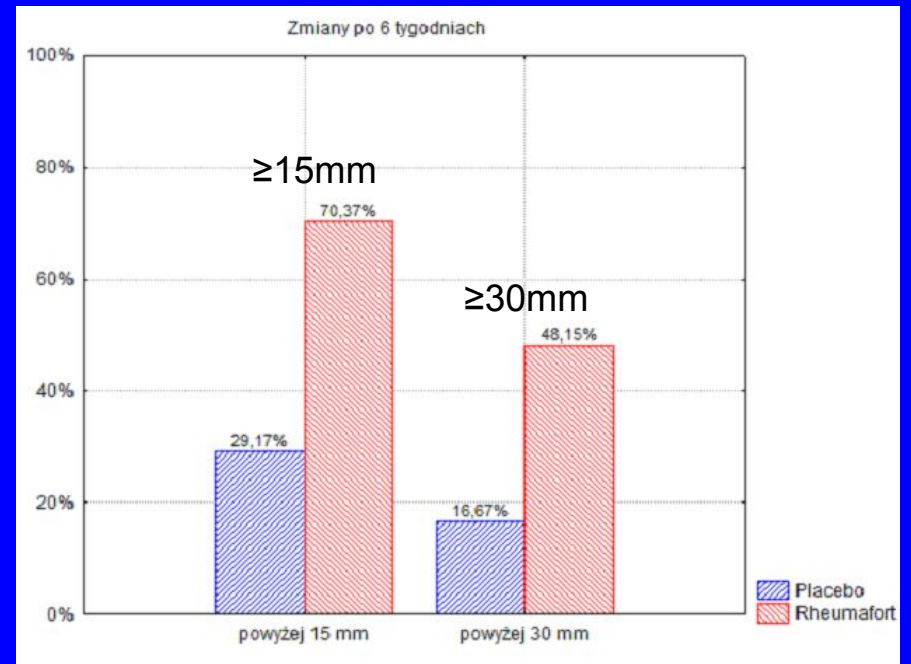


Mean value  $\pm$  2SEM

# % of patients with significant pain reduction within 24 hrs

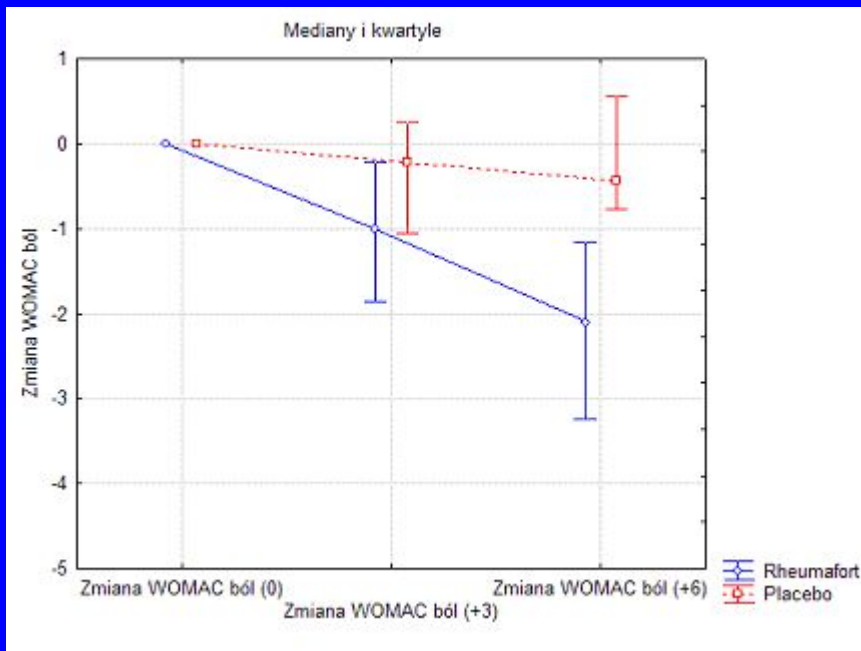


After 3 weeks

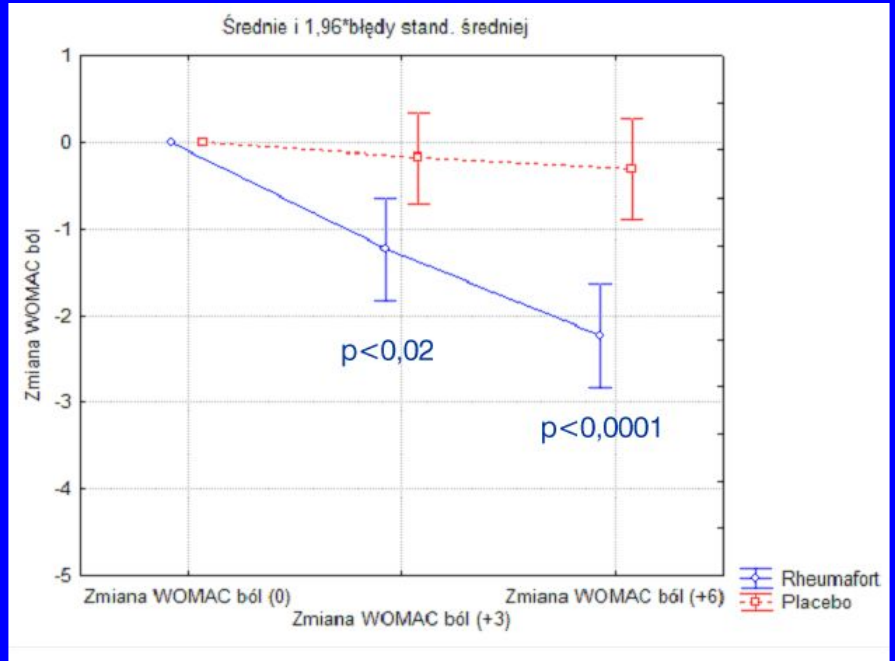


After 6 weeks

# Reduction of joint pain WOMAC

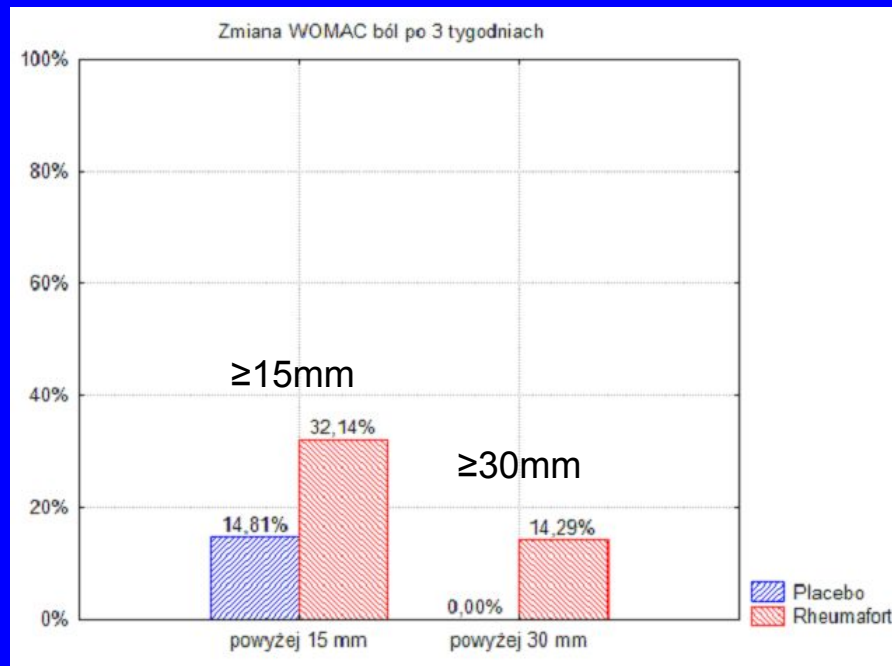


Median  $\pm$  quartile<sub>2,3</sub>

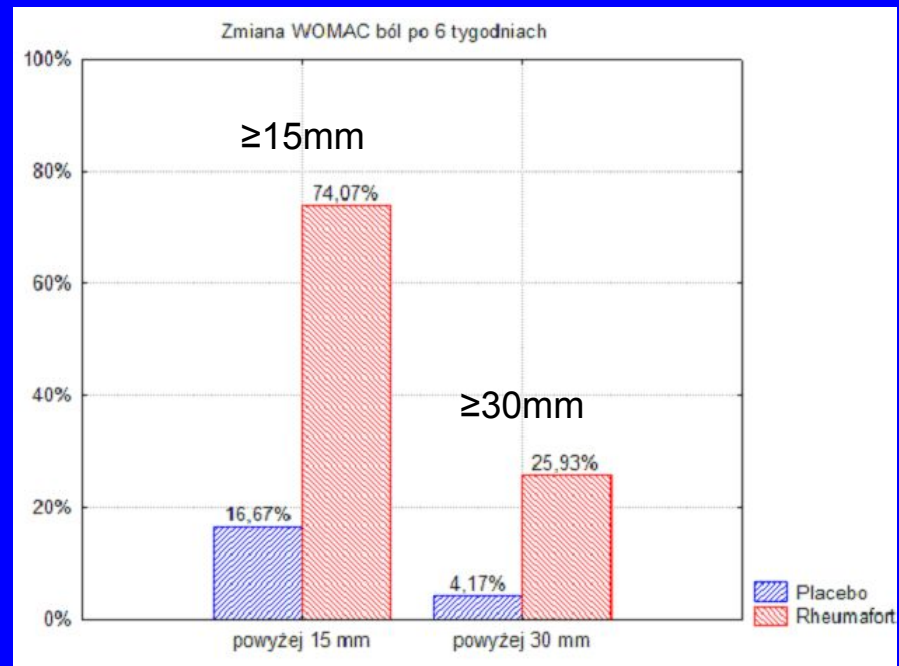


Mean value  $\pm$  2SEM

# % of patients with significant pain reduction in WOMAC

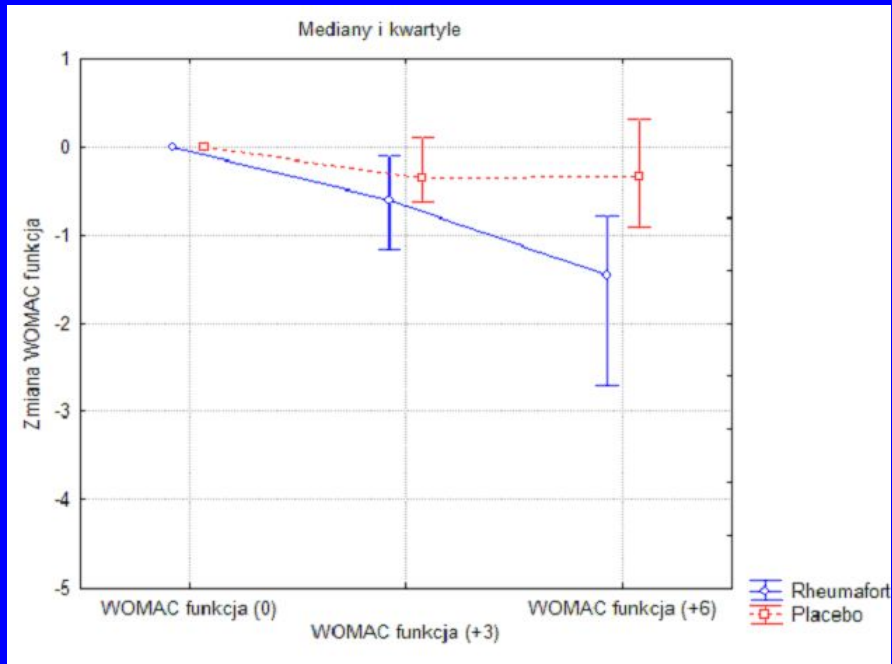


After 3 weeks

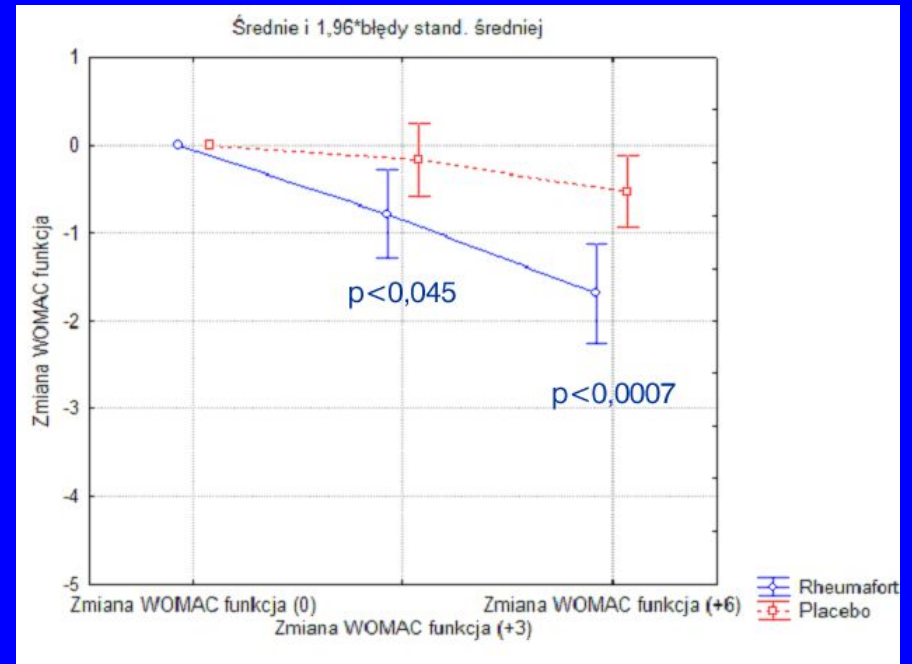


After 6 weeks

# Improvement of joint function in WOMAC



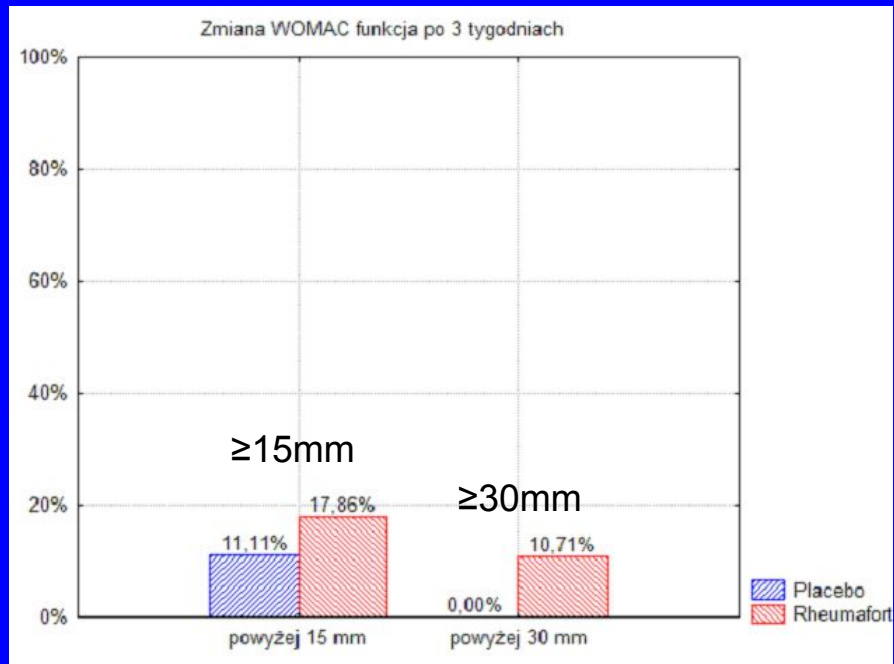
Median  $\pm$ quartile2,3



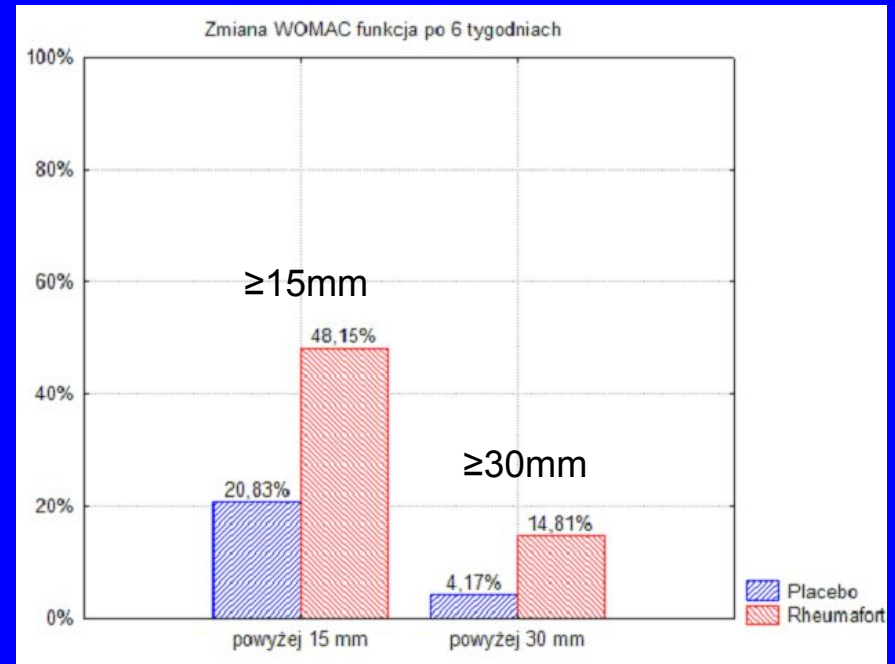
Mean value  $\pm$ 2SEM



# % of patients with significant joint function improvement in WOMAC



After 3 weeks



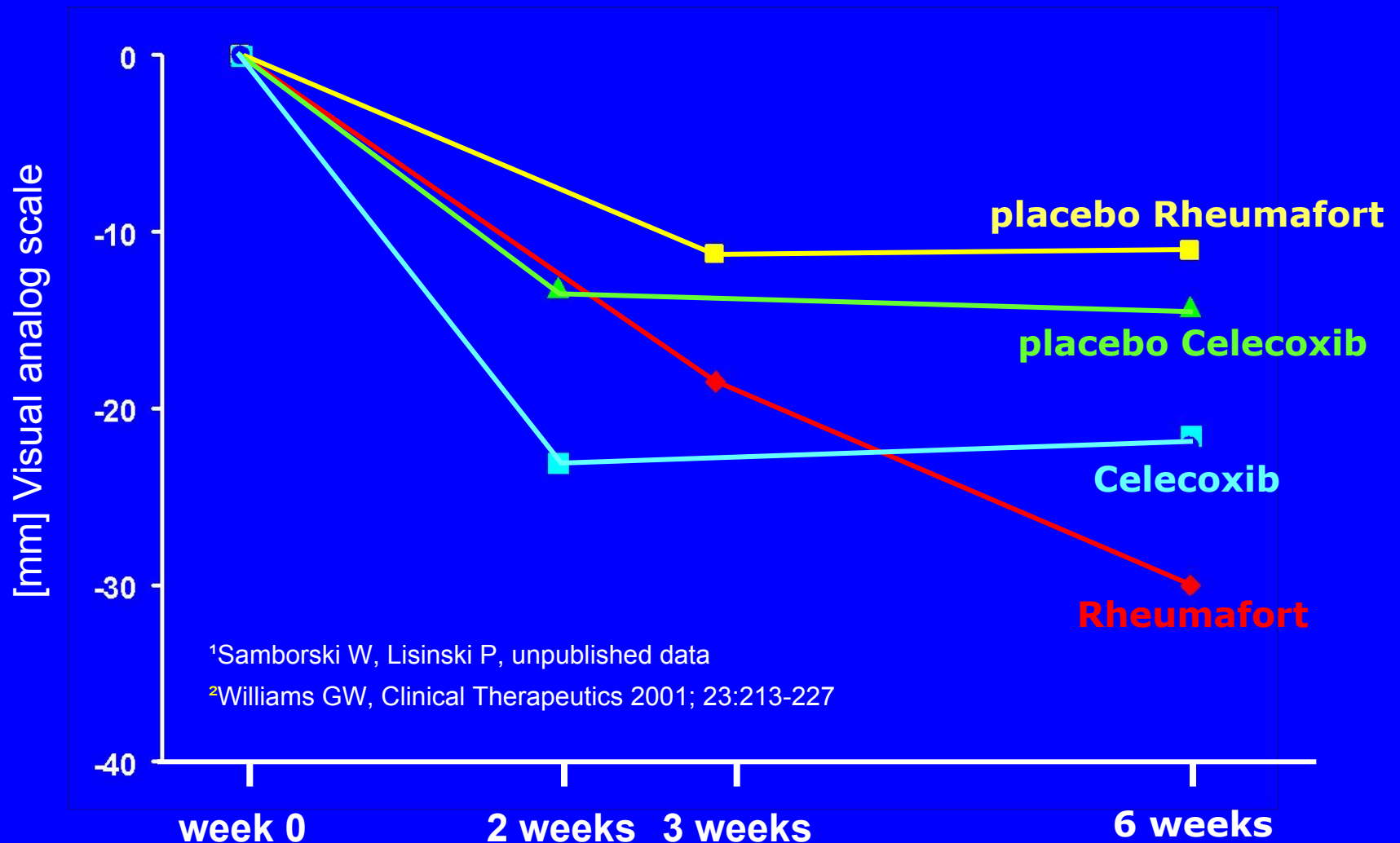
After 6 weeks

**What is Rheumafort's  
effectiveness when compared  
with other NSAID's?**

**Comparison of the Rheumafort  
study with the Celecoxib study is  
made according to similar  
protocol**

# Reduction of joint pain

Rheumafort study<sup>1</sup> compared with Celecoxib study<sup>2</sup>



# Conclusions

- ❑ Rheumafort (Arthritol) shows fast and statistically significant effects in osteoarthritis patients on:
  - Joint pain reduction
  - Stiffness reduction
  - Joint function improvement
- ❑ No significant side effects of Rheumafort have been noticed