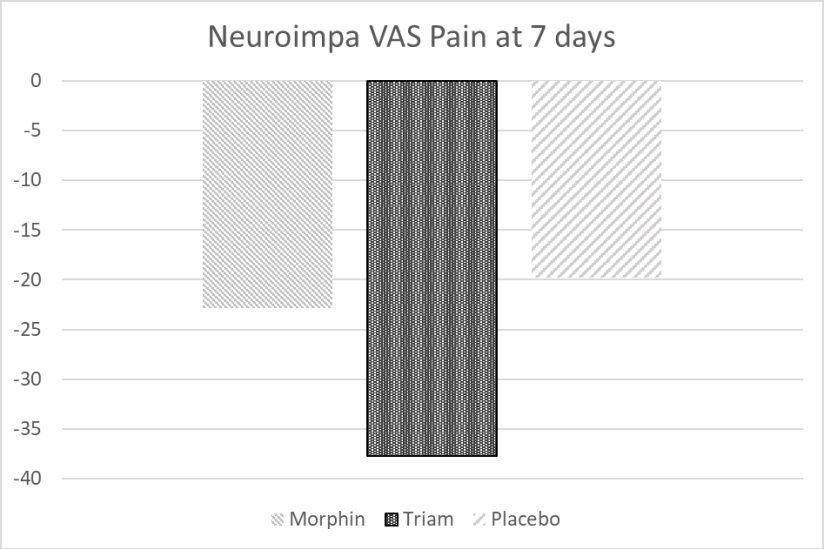
Primary Endpoint: Difference VAS Spain Score (mm) between the value at 8 a.m. on day 7 and baseline.

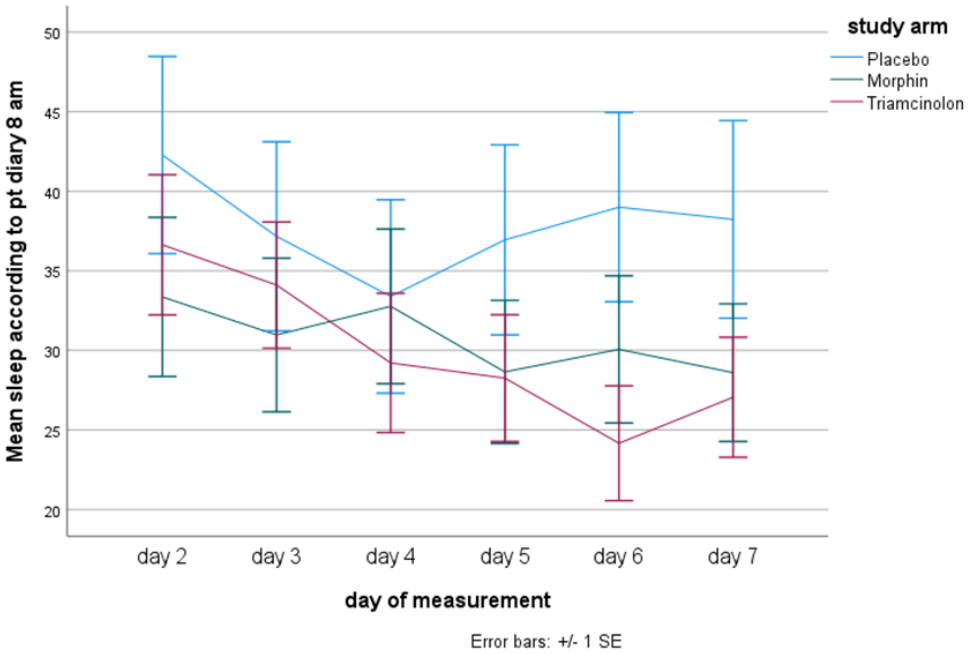


The primary endpoint was the difference in mm VAS between the value at 8 a.m. on day 7 and baseline. There were no differences between study arm (p=0.41) or diagnostic group (p=0.84) at baseline. At day 7, adjusted for baseline, there was no difference between diagnostic groups (p=0.63), and Morphine and Placebo (p=1.0), whereas results of Triamcinolone were significantly smaller than Placebo (p=0.005), and Morphine (p=0.004). In conclusion, the primary endpoint was not met.

Secondary Endpoints:

1. **VAS quality of sleep according to patient diary**
   There were no differences between study arm (p=0.24) or diagnostic group (p=0.32) (average day 2 to day 7)

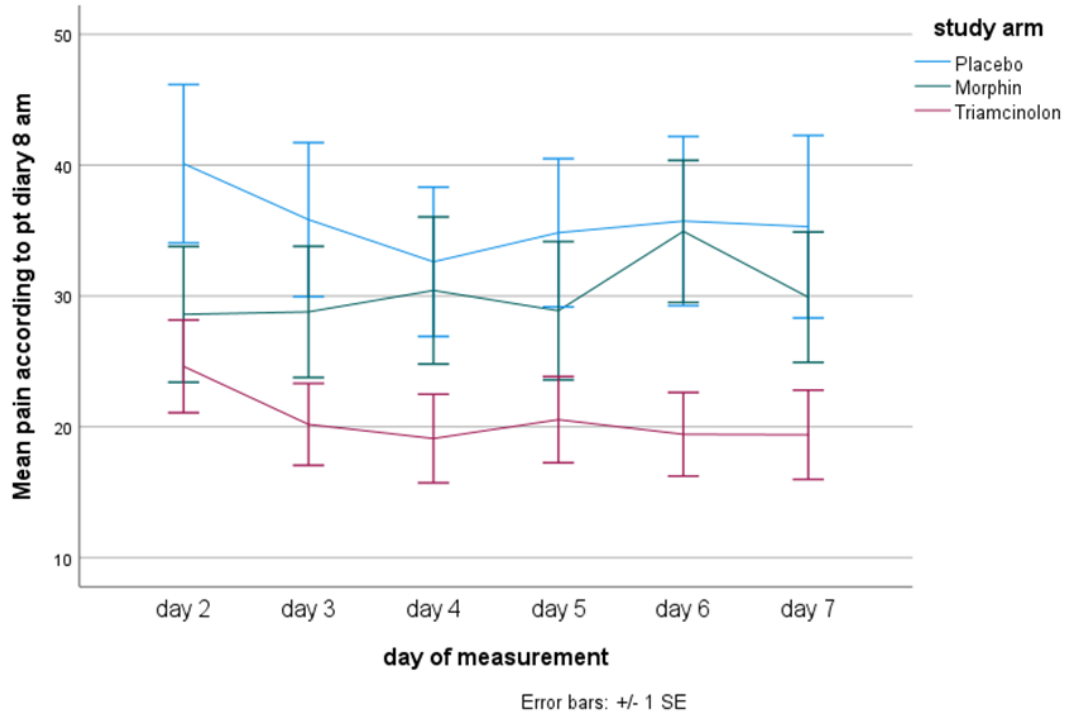
Figure 4: sleep according to patient diary



2. VAS pain according to patient diary

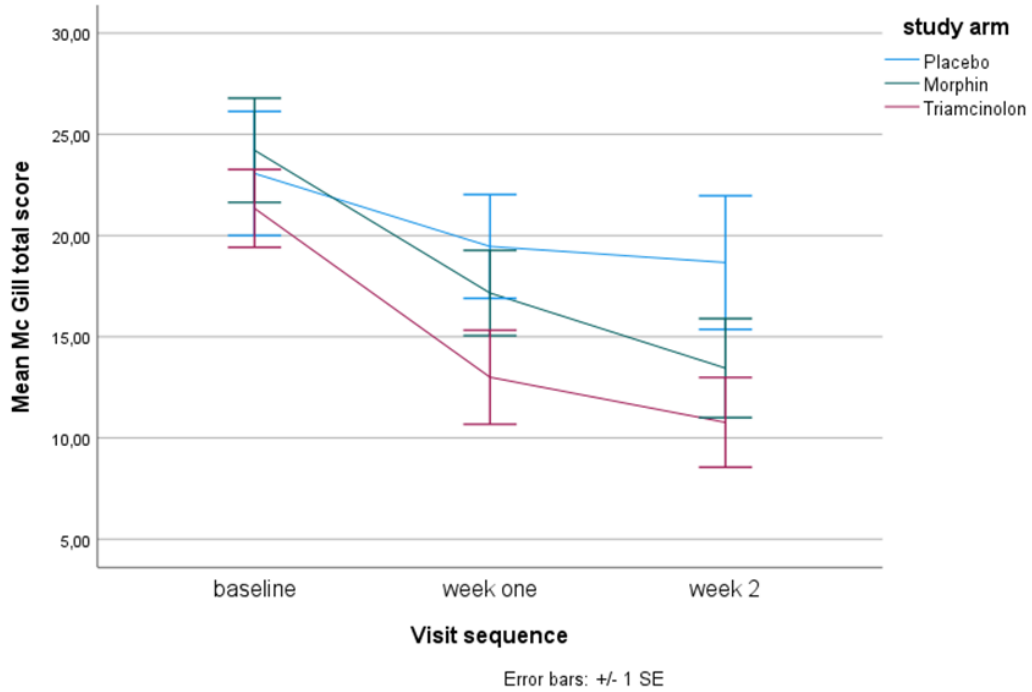
There were no differences between study arm (p=0.071) or diagnostic group (p=0.88) (average day 2 to day 7). However, Triamcinolone showed a tendency to smaller values than Morphine (uncorrected p = 0.026) and Placebo (uncorrected p = 0.073).

Figure 5: pain according to patient diary



3. McGill pain questionnaire

Figure 6: McGill patient questionnaire



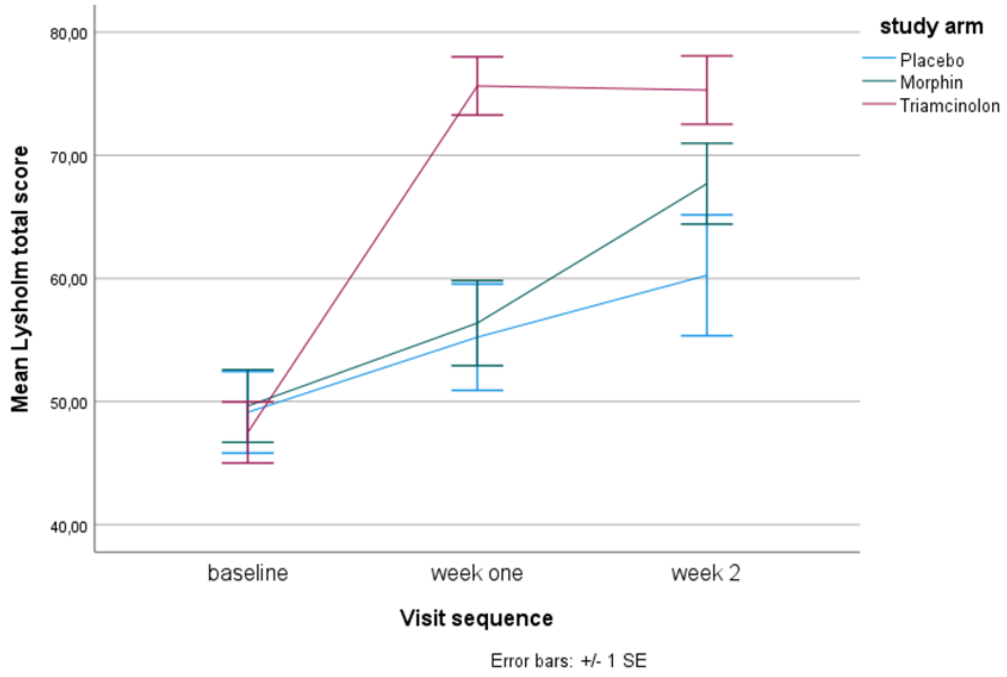
The McGill pain questionnaire consists of 20 groups of words, related to different types of pain

(sensory, affective, evaluative, miscellaneous types of pain), each item can be marked with weights from 1 = mild, 2 = medium to 3 = severe, leading to a range from 0 to 100. There were no differences between study arms (p=0.89) at baseline. There was a trend to higher values for arthrosis as compared to arthritis (p=.055) at baseline. At day 7, adjusted for baseline, there was no difference between study arm (p=0.44) and diagnostic groups (p=0.95). At day 14, adjusted for baseline, there was no difference between study arms (p=0.74) and diagnostic groups (p=0.69).

4. Knee activity and mobility (Lysholm Gilquist-score)

The Lysholm Gilquist score was designed to give information as to how the knee problems have affected the ability to manage in everyday life. The range of the score is 0 to 100, with higher values mean better wellbeing, and has different weights to different items.

Figure 7: Lysholm Gilquist-score



There were no differences between study arm (p=0.45) or diagnostic group (p=0.38) at baseline. At day 7, adjusted for baseline, there was no difference between diagnostic groups (p=0.67), and Morphine and Placebo (p=0.84), whereas results of Triamcinolone were significantly larger (i.e. better) than Placebo (p<0.001), and Morphine (p<0.001). At day 14, adjusted for baseline, there was no difference between diagnostic groups (p=0.88), and Morphine and Placebo (p=0.20), whereas results of Triamcinolone were significantly larger (i.e. better) than Placebo (p=0.006), and there was a trend to larger values vs. Morphine (p=0.08).

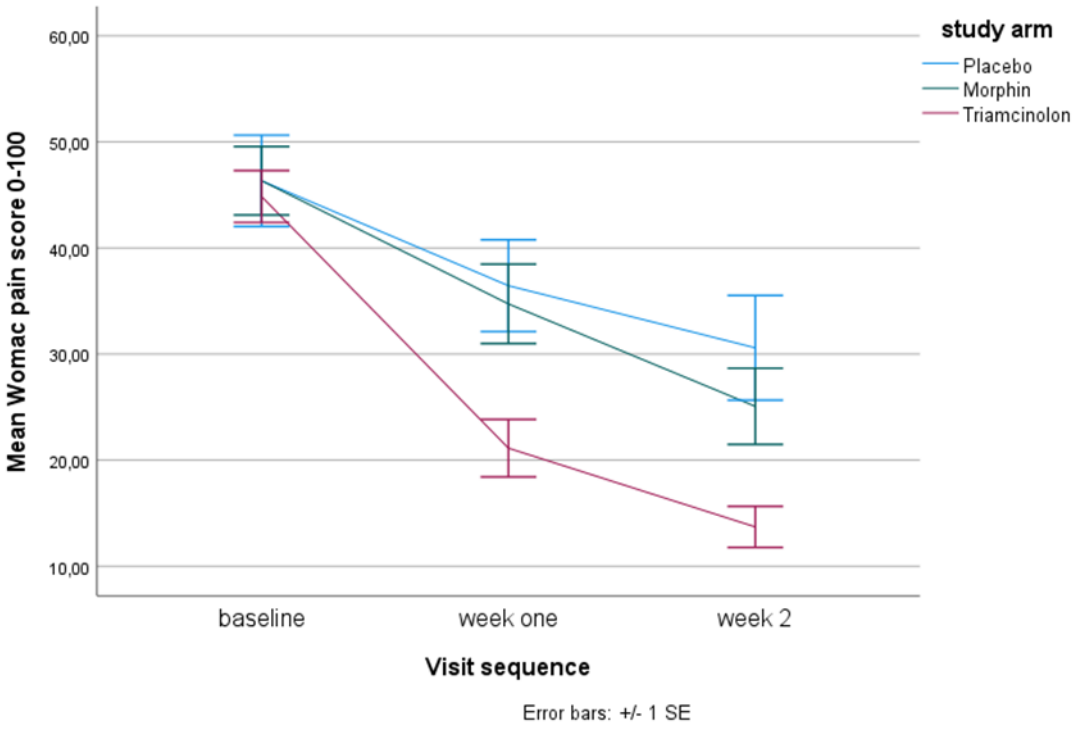
5. WOMAC Index Pain

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) is a widely used, proprietary set of standardized questionnaires used by health professionals to evaluate the condition of patients with osteoarthritis of the knee and hip, including pain, stiffness, and physical functioning of the joints. Higher scores indicate worse pain, stiffness, and functional limitations. The WOMAC

measures five items for pain (score range 0–20), two for stiffness (score range 0–8), and 17 for functional limitation (score range 0–68) [2].

There were no differences between study arm (p=0.76) or diagnostic group (p=0.63) at baseline. At day 7, adjusted for baseline, there was no difference between diagnostic groups (p=0.38), and Morphine and Placebo (p=0.78), whereas results of Triamcinolone were significantly smaller than Placebo (p=0.003), and Morphine (p=0.004). At day 14, adjusted for baseline, there was no difference between diagnostic groups (p=0.26), and Morphine and Placebo (p=0.36), whereas results of Triamcinolone were significantly smaller than Placebo (p=0.004), and Morphine (p=0.005).

Figure 8: Womac pain score

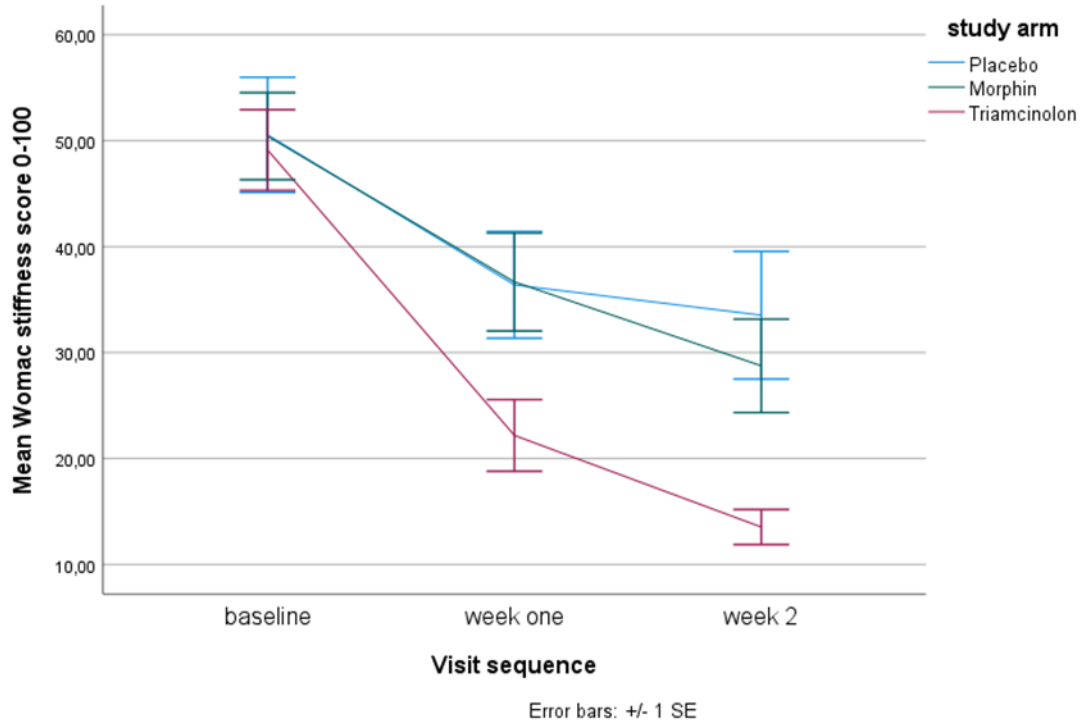


6. WOMAC stiffness

There were no differences between study arm (p=0.94) or diagnostic group (p=0.84) at baseline. At day 7, adjusted for baseline, there was no difference between diagnostic groups (p=), and Morphine and Placebo (p=0.97), whereas results of Triamcinolone were significantly smaller than Placebo (p=0.022), and Morphine (p=0.012).

At day 14, adjusted for baseline, there was no difference between diagnostic groups (p=), and Morphine and Placebo (p=0.52), whereas results of Triamcinolone were significantly smaller than Placebo (p=0.005), and Morphine (p=0.003).

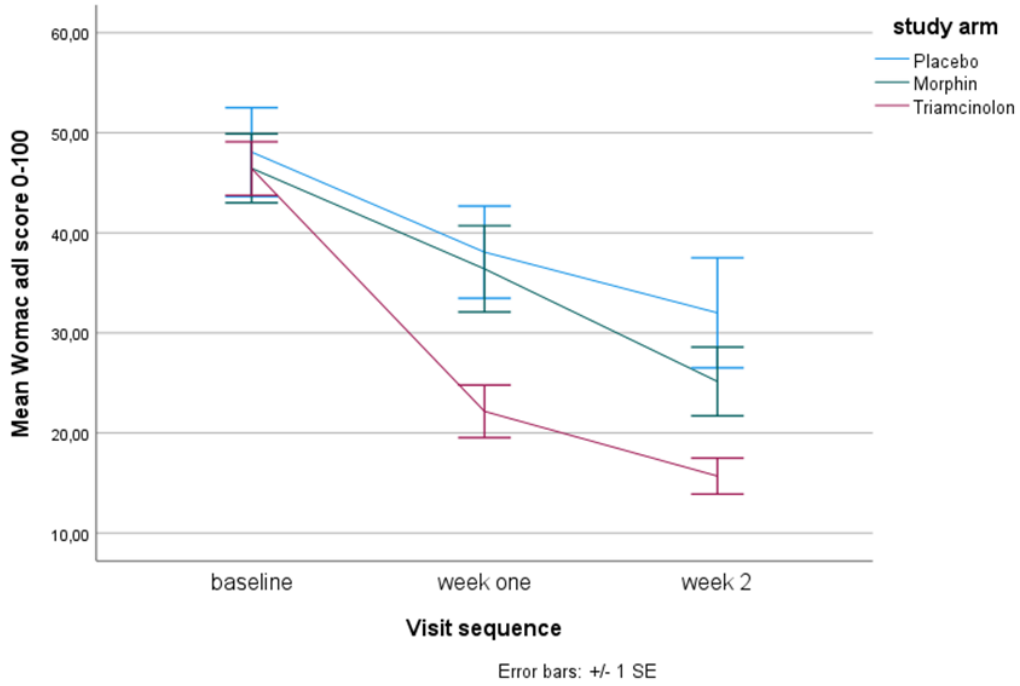
Figure 9: WOMAC stiffness



7. WOMAC physical activity score

There were no differences between study arm (p=0.85) or diagnostic group (p=0.83) at baseline. At day 7, adjusted for baseline, there was no difference between diagnostic groups (p=0.18), and Morphine and Placebo (p=0.81), whereas results of Triamcinolone were significantly smaller than Placebo (p=0.002), and Morphine (p=0.007). At day 14, adjusted for baseline, there was no difference between diagnostic groups (p=0.20), and Morphine and Placebo (p=0.27), whereas results of Triamcinolone were significantly smaller than Placebo (p=0.011), and Morphine (p=0.019).

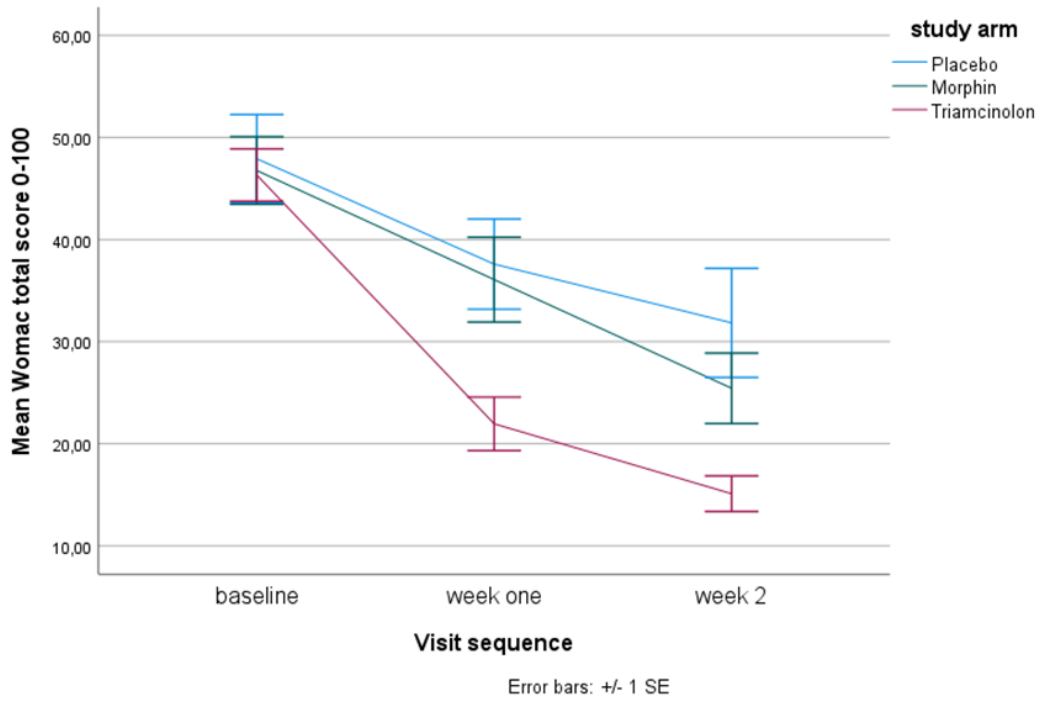
Figure 9: Womac physical activity score



8. WOMAC total score

There were no differences between study arm (p=0.88) or diagnostic group (p=0.79) at baseline. At day 7, adjusted for baseline, there was no difference between diagnostic groups (p=0.23), and Morphine and Placebo (p=0.82), whereas results of Triamcinolone were significantly smaller than Placebo (p=0.002), and Morphine (p=0.004). At day 14, adjusted for baseline, there was no difference between diagnostic groups (p=0.24), and Morphine and Placebo (p=0.30), whereas results of Triamcinolone were significantly smaller than Placebo (p=0.008), and Morphine (p=0.007).

Figure 10: Womac total score



9. Inflammatory parameters (C-reactive protein)

To obtain normally distributed data, raw CRP values were transformed according to the formula CRP transformed = lg10(CRPraw+1). There were no differences between study arm (p=0.41) at screening. Values for arthritis were significantly larger than for arthrosis (p=0.001) at this visit. At day 7, adjusted for baseline, there was no difference between diagnostic groups (p=0.13) , and Morphine and Placebo (p=0.22), whereas results of Triamcinolone were significantly smaller than Placebo (p=0.011), and Morphine (p=0.015).

Figure 11: C-reactive protein