Rheumatology and Therapy

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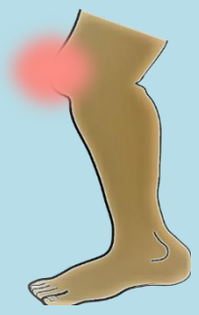
Safety and Efficacy of Repeat Administration of Triamcinolone Acetonide Extended-Release in Osteoarthritis of the Knee: A Phase 3b, Open-label Study

Spitzer, A.I., Richmond, J.C., Kraus, V.B. et al. Rheumatol Ther (2019) 6: 109. https://doi.org/10.1007/s40744-019-0140-z

Study Location

USA

Indication



Knee OA

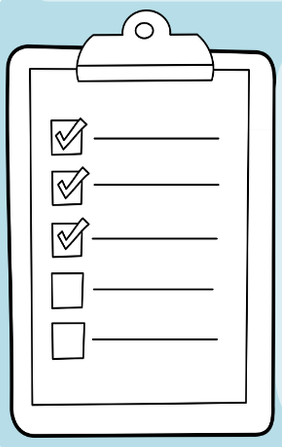
Study Population

208 patients

Study Design

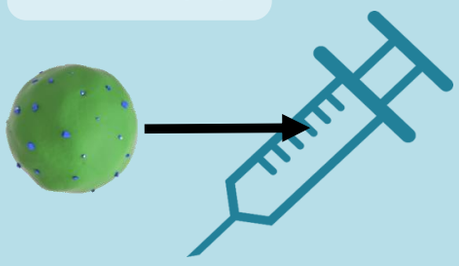
Phase 3b, single-arm, open-label

Inclusion Criteria



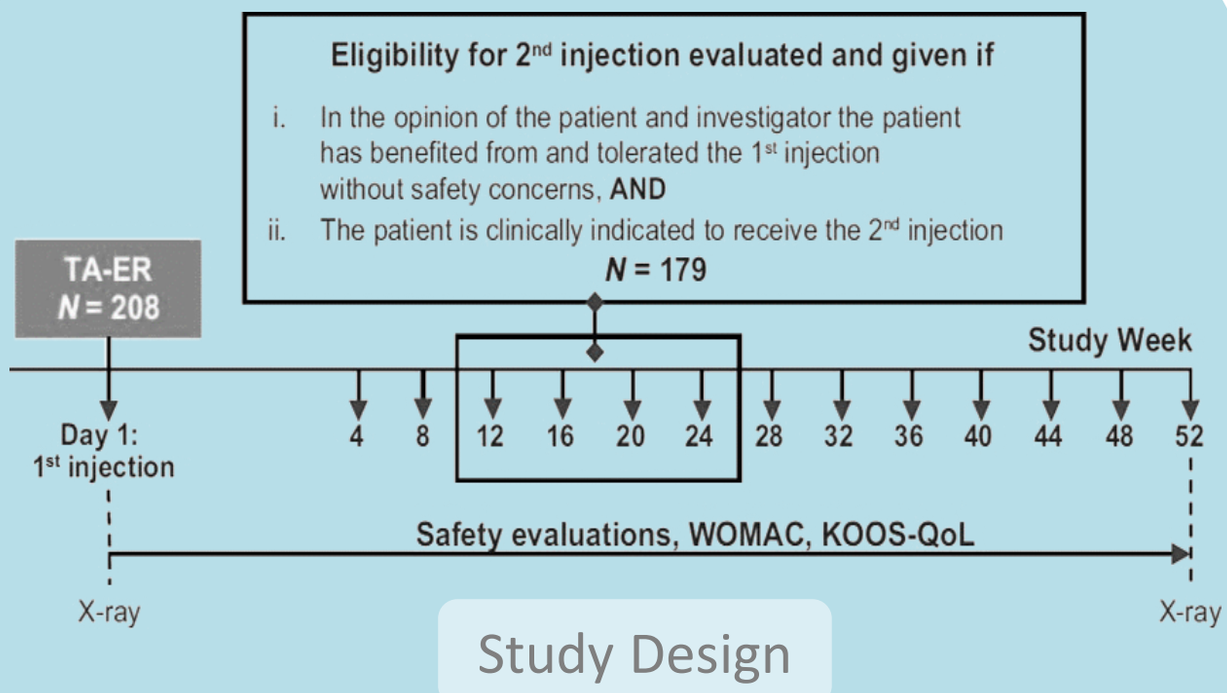
- Age ≥ 40 years
- Knee OA per ACR criteria
- OA symptoms ≥ 6 months
- Index-knee pain > 15 days in the past month
- WOMAC-A (pain) total sum ≥ 6

Therapy



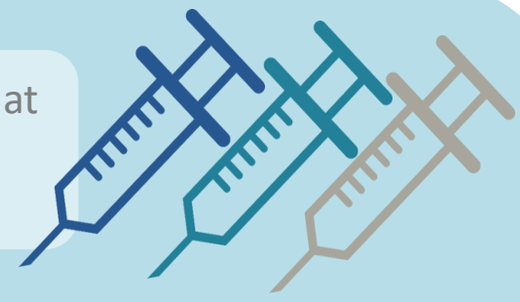
Triamcinolone Acetonide Extended-Release, a novel poly(lactic-co-glycolic acid) microsphere-based formulation of triamcinolone acetonide

Study Design



Why carry out this study?

Many patients receive repeated doses of IA **corticosteroids** to manage knee pain related to OA due, at least in part, to the rapid efflux from the joint of traditional corticosteroid crystalline suspensions.



Single IA injections of the extended-release formulation of **triamcinolone acetonide extended-release** (TA-ER) demonstrated prolonged joint residency times and sustained, clinically relevant benefit in patients with **knee OA**.

This study was conducted to assess the **safety** and exploratory **efficacy** of repeat administration of TA-ER. It utilized a flexible dosing interval for patients to receive a 2nd injection based on duration of benefit from the 1st injection. The patient population included in this study was reflective of those seen in "real-world" clinical practice.

What was learned from the study?

Safety

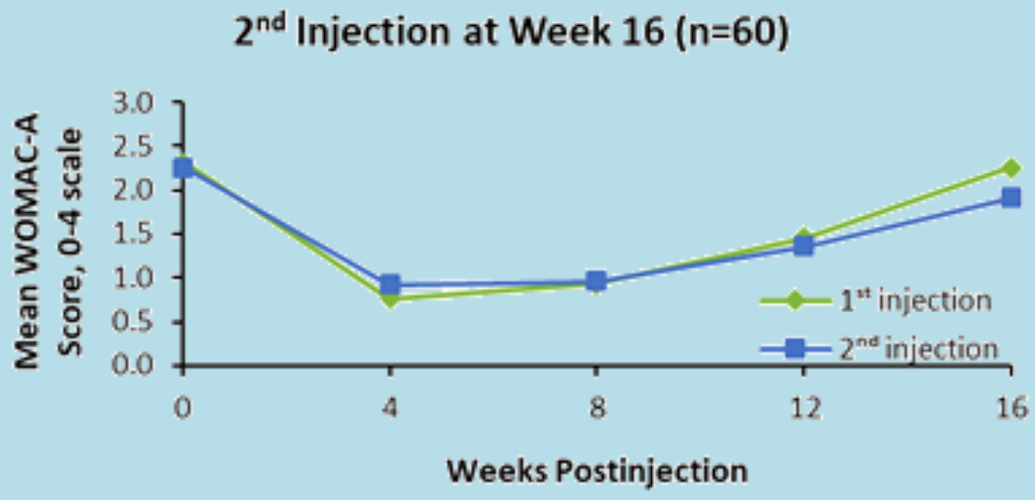
The **safety** profile was similar between the 1st and 2nd injections, with no unexpected adverse events or significant radiographic changes at Week 52.

Duration

86.1% of patients received the 2nd injection, with a median time to 2nd injection of **16.6 weeks**.

Response Improvement

Through 12 weeks after both injections, the magnitude and duration of clinical benefit were similar, and most patients reported a substantial (≥50% improvement) analgesic response.



Comparison of mean WOMAC-A (pain) scores following the 1st and 2nd TA-ER injections for patients who received the 2nd injection at Week 16 (*N* = 60) (efficacy population)

Abbreviations: OA = Osteoarthritis; ACR = American College of Rheumatology; IA = intra-articular; WOMAC-A = Western Ontario and McMaster Universities Osteoarthritis Index