OARSI CONNECT '21
VIRTUAL WORLD CONGRESS ON OSTEOARTHRITIS

POLYACRYLAMIDE HYDROGEL INJECTION FOR KNEE OSTEOARTHRITIS: RESULTS OF A 52 WEEK PROSPECTIVE STUDY

Poster 336

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OBJECTIVE

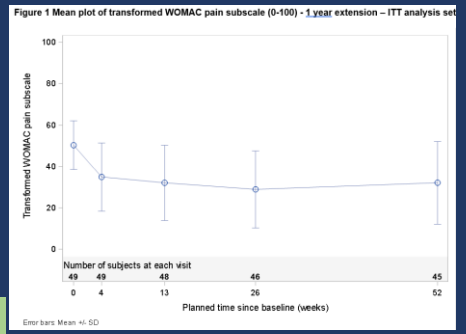
- Intra-articular (IA) injection of polyacrylamide hydrogel (PAAG) has been suggested as a possible treatment for symptomatic osteoarthritis (OA)
- PAAG has been investigated using 2 injections of 3 ml separated by a month
- The primary objective of this study was to evaluate the efficacy and safety of a single injection of 6 ml intra-articular PAAG on knee symptoms in participants with moderate to severe knee OA.

METHODS

- Patients with symptomatic (WOMAC A1 ≥2/4 Likert) and radiographic (KL grade 2 to 4) knee OA were consented into this prospective, open-label study
- 2.5% cross-linked PAAG was used. PAAG (Contura International A/S) contains 2.5% polyacrylamide and 97.5% non-pyrogenic water, with a unique molecular structure that allows normal water exchange with the surrounding tissue without losing shape. PAAG is bioallcompatible, non-absorbable, non-biodegradable, stable, and sterile.
- PAAG was provided in sterile, pre-filled 1 ml sealed syringes to be injected intra-articularly with a sterile 21G x 2-inch (0.8 x 50 mm) needle. PAAG is classified as a Class IIb device
- Primary outcome was change in WOMAC pain subscale (normalized to 100 points) after 12 weeks
- Secondary outcomes were WOMAC stiffness and function subscales, Patient Global Assessment of disease impact (PGA) and proportion of OMERACT-OARSI responders.
- Follow-up : 4, 12, 26 and 52 weeks

RESULTS

- 49 patients (31 females) received IA PAAG, and 48 and 46 completed the 12 and 52 week assessments, respectively
- There were statistically and clinically significant reductions in WOMAC pain after 12 weeks (mean change -18.3 points [95% CI: -23.3 to -13.3]; P<.0001), sustained to 52 weeks (mean change -20.8 points [95% CI -26.3 to -15.3]; P<0.0001) [Figure 1]
- Similar benefits were found for WOMAC stiffness, function [Figure 2,3], and patient global assessment. After 12 weeks, 64.6% of patients were OMERACT-OARSI responders, also maintained to 52 weeks
- In the initial 12 weeks, 18 patients reported 23 AEs; 13 events were related to PAAG (most frequent: arthralgia and joint swelling) and not considered serious. No new PAAG related AEs were observed from 12 to 52 weeks. Three serious AEs occurred (atrial fibrillation, gastrointestinal pain and cerebrovascular event) all assessed as 'not related' to PAAG



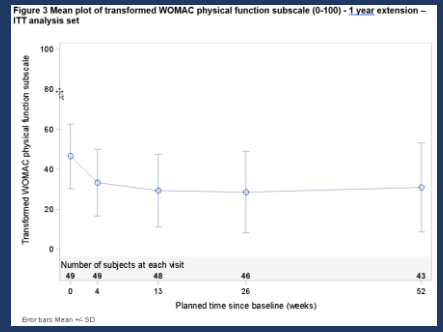


Table: Adverse events in target joint registered during the 12 months – ITT analysis set
N=subject, (%), E=total number of events

Preferred term	All events N (%) E	Device relevant N (%) E
Arthralgia	8 (16) 10	6 (12) 6
Swelling	5 (10) 5	4 (8) 4
Cyst	3 (6) 3	3 (6) 3
Pain in the leg	1 (2) 1	1 (2) 1

Treatment emergent adverse events by system organ class and preferred term – 12 mths - ITT analysis set

System organ class Preferred term	PAAG-OA N (%) E
ITT analysis set N (%)	49 (100.0)
N=subject, (%), E=total number of events	
Any adverse events	25 (51) 39
Musculoskeletal and connective tissue disorders	19 (39) 24
Arthralgia	8 (16) 10
Joint swelling	5 (10) 5
Synovial cyst	3 (6) 3
Back pain	1 (2) 1
Bursitis	1 (2) 1
Joint effusion	1 (2) 1
Joint stiffness	1 (2) 1
Musculoskeletal pain	1 (2) 1
Pain in extremity	1 (2) 1
Metabolism and nutrition disorders	4 (8) 4
Hyperlipidaemia	2 (4) 2
Diabetes mellitus	1 (2) 1
Gout	1 (2) 1
Infections and infestations	3 (6) 3
Nasopharyngitis	2 (4) 2
Skin infection	1 (2) 1
Gastrointestinal disorders	2 (4) 2
Abdominal pain	1 (2) 1
Gastrooesophageal reflux disease	1 (4) 1
Skin and subcutaneous tissue disorders	1 (2) 2
Eczema	1 (2) 1
Psoriasis	1 (2) 1
Cardiac disorders	1 (2) 1
Atrial fibrillation	1 (2) 1
Injury, poisoning and procedural complications	1 (2) 1
Upper limb fracture	1 (2) 1
Nervous system disorders	1 (2) 1
Cerebrovascular accident	1 (2) 1
Vascular disorders	1 (2) 1
Hypertension	1 (2) 1

CONCLUSION

PAAG can be delivered in a single injection and this non-randomized trial suggests that the good clinical effects at 12 weeks were maintained at 52 weeks in patients with moderate to severe knee OA. These encouraging results need to be confirmed in controlled studies.

Ref: Bliddal H, Overgaard A, Hartkopp A, Beier J, Conaghan PG, Henriksen M: Polyacrylamide Hydrogel Injection for Knee Osteoarthritis: A 6 Months Prospective Study. Journal of Orthopedic Research and Therapy 2021;6:1-9.
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