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Dyve Biosciences

Pilot, Randomized, Double-Blinded, Placebo Controlled Efficacy and Safety Study of a Transdermal Alkalinizing and Pain Relieving Treatment for Acute Gout Pain

Objectives: Gout is characterized by a build-up of monosodium urate (MSU) crystals in and around the joints. MSU crystal formation and dissolution is affected by pH. There are reports in the literature of the use of alkalization agents, such as sodium bicarbonate, to treat gout. Theoretically, an alkalinizing agent such as sodium bicarbonate (baking soda) may increase the systemic and/or local pH and may allow pH sensitive uric acid crystals to dissolve resulting in temporary relief of pain and shortening duration of a gout flare, however oral sodium bicarbonate use causes intolerable gastrointestinal side-effects. The objective of this study was to determine if sodium bicarbonate in a patented transdermal drug delivery system (Dyve Biosciences, Thousand Oaks, CA) can effectively and safely reduce pain and shorten duration of an acute gout flare. This delivery system has been shown to effectively deliver sodium bicarbonate transdermally in prior animal and human studies.

Status: This study has been completed.

Methodology: This pilot study is prospective, double-blinded, randomized, and placebo-controlled in design. Twenty-four subjects, female and male, aged 18+, with clinical diagnosis of gout, history of uric acid >6.8mg/dl, on stable medication regimen, presenting in clinic within 36 hours of initiation of acute gout attack and prescribed 0.6 mg/daily colchicine were included. Non-inclusion criteria included >stage 3 kidney disease, tophaceous gout, and recent/concurrent initiation of other pain medications (e.g. NSAID, corticosteroids). Subjects were randomized to receive placebo lotion or sodium bicarbonate transdermal lotion (33% sodium bicarbonate and 0.5% menthol) and instructed to apply to the entire limb of up to three affected joints (target joint and up to two other joints). Outcome measures included pain (numeric rating scale, 0-10), time to resolution (50% reduction in pain), range of motion and subject satisfaction. Time-points were baseline,15 & 30 min, and 1,2,4,6,8,10,12, and 14 days. Adverse events were collected. Statistical analysis was repeated measures ANOVA with $p<0.05$ as significant.

Findings: The active treatment subjects (N=12) had pain scores that averaged about 1.3 points lower than the placebo patients (N=12) ($p=0.0041$). Figure 1 shows the % reduction in pain scores over time in the target joint. The secondary joint (N=9 for both groups) also had a significant ($p=0.04$) reduction in pain with average pain of 1.2 points lower than control. The mean time to resolution for the target joint was 4.1 days in placebo group and 2.2 days in the active group. The mean time to resolution for the secondary joint was 2.8 days in the control group and 1.6 days in the active group. Among those who attained improved ROM, average time was 2.5 days in placebo group and 1.7 days in active group.

Subject satisfaction was 55.6% in control and 85.7% in active. No treatment related adverse events reported.

Significance: Topical transdermal sodium bicarbonate lotion use resulted in a highly significant (p=0.0041) reduction in pain, as early as 15 min, and may speed resolution of acute gout attacks and improvement of range of motion.

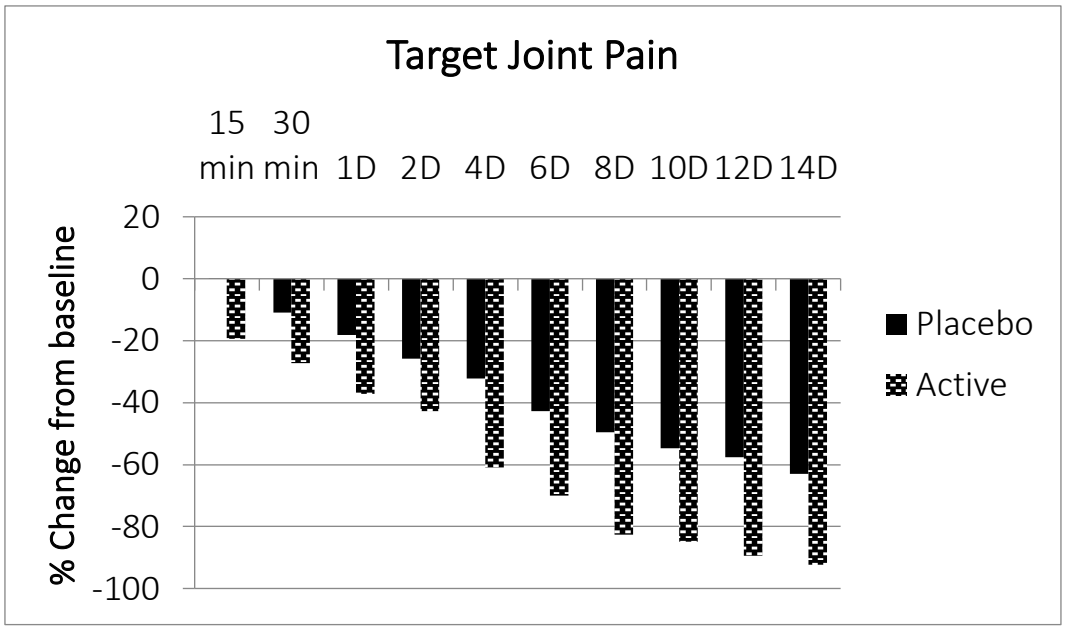

Figure 1. The subject's "target joint" was the joint chosen by the investigator as the joint with the most severe pain and similar feeling to previously experienced gout pain. This figure shows the percent reduction in pain at each follow-up time point compared to baseline pain on a numeric 0-10 scale with 0=no pain and 10=the worst possible pain.