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Peripheral Neuropathic Pain (PNP):
- Management of PNP is a significant challenge.
- Currently the most difficult pain to treat.
- Current therapies have a limited effect on PNP and can cause side effects.
- Recent research indicates that cannabinoids have therapeutic potential.
- The study aimed to evaluate the long term efficacy of Sativex in relieving chronic PNP and to assess the safety of Sativex in study patients with PNP associated with allodynia.

Study drug: Sativex® (THC:CBD) endocannabinoid system modulator.
- Derived from highly standardised botanical extract.
- Formulated into a spray for sublingual/oromucosal administration.
- Highly standardised formulation, each 100µl spray of Sativex® contains 2.7 mg Δ9-tetrahydrocannabinol (THC), 2.5 mg cannabidiol (CBD), and small amounts of other cannabinoids.
- Approved in Canada for relief of central neuropathic pain in MS and cancer pain.

INTRODUCTION

Methods

A 15-week (two-week baseline and 14-week treatment period), multicentre, double-blind, randomised, placebo controlled parallel group study.
- Patients randomised to either Sativex or placebo and self-titrated study medication based on efficacy and tolerability, up to a maximum of 24 sprays/day.
- Patients had chronic pain (six months) PNP associated with allodynia, and secondary to post-herpetic neuritis, peripheral neuropathy or focal nerve lesion or Complex Regional Pain Syndrome type 2.

PrimaryEndpoints:
- Change from baseline in 0-10 NRS pain severity scores
- Responders analysis (30% decrease in 0-10 NRS pain severity score from baseline)

SecondaryEndpoints:
- Neurological pain scale (NPS)
- Brief pain inventory (BPI)
- Sleep quality 0-10 NRS
- Subject global impression of change (SGIC)
- Quality of life questionnaire (EQ-5D)
- Rescue analgesic use
- Adverse Event (AE) monitoring

RESULTS

Patient Disposition
- Screened (n=303)
- Randomised (n=246)
- Safety set (n=246)
- Completed (n=94)
- Withdrawn (n=24): AE (7), withdrew (3), lost to follow-up (1)
- Other (1)

The two treatment groups were closely matched for all demographic and baseline characteristics.

Primary Endpoints:
- The pain responder analysis was statistically significant in favour of Sativex with an odds ratio of 1.97.
- The change in pain 0-10 NRS from baseline was -1.05 for Sativex and -0.71 for placebo, the proportion of responders was much more quickly in relation to the dose.
- There was a statistically significant treatment difference for a positive response in favour of Sativex.
- The estimated treatment difference of -0.83 points in favour of Sativex was highly statistically significant (p=0.015).
- There were no signs of tolerance; pain relief was maintained without an increase in dose.

Secondary Endpoints:
- Sleep Quality Assessment
- The adjusted mean sleep quality rating score for the Sativex group showed an improvement of 1.57 points from a mean baseline score of 5.4 points, compared with an adjusted decrease of 0.74 points from a baseline of 5.8 points for placebo.
- The estimated treatment difference of -0.83 points in favour of Sativex was highly statistically significant (p=0.015).
- On average, Sativex group used fewer doses of rescue analgesic than the placebo group.
- On average, the Sativex group used fewer spray of study medication than the placebo group.

SafetyEndpoints:
- Adverse Event (AE) monitoring

DISCUSSION

These data support the efficacy of Sativex in relieving PNP and substantiate its safety profile in patients.
- Sativex improved both the pain and sleep parameters measured.
- There were no signs of tolerance; pain relief was maintained without an increase in dose.

CONCLUSION


CONFICT OF INTEREST: This trial was sponsored and fully funded by GW Pharma Ltd. Investigators received research grants to cover the costs of the study.