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Abstract Book



Basic Science

Exploring the Therapeutic Potential of Cannabinoid-Rich Extracts from Białobrzaska Industrial Hemp

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Abstract Text: Background: Industrial hemp, specifically the Białobrzaska variety, is primarily cultivated for its fiber, yet it also contains various cannabinoids, including CBD, CBG, CBN, THC, and CBC. This study investigates the extraction, composition, and potential therapeutic applications of these cannabinoids.

Objectives: The study aims to determine the cannabinoid content of Białobrzaska industrial hemp extracts (1-9) and evaluate their antioxidant, neuroprotective, and prebiotic properties.

Methods: Supercritical fluid extraction (SFE) was employed under critical process conditions to obtain extracts enriched in cannabinoids. The antioxidant activity was assessed using multiple in vitro models. Inhibitory effects on acetylcholinesterase (AChE) and butyrylcholinesterase (BChE) were also evaluated. Additionally, systems with prebiotic potential were prepared using dextran, inulin, and trehalose as carrier substances.

Results: Extract 9, characterized by the highest cannabinoid content, exhibited significant antioxidant activity and the most pronounced inhibitory effects against AChE and BChE. The prebiotic systems maintained active compound content, antioxidant activity, and cholinesterase inhibitory effects.

Conclusion: Our findings suggest that Białobrzaska industrial hemp extracts, particularly extract 9, possess therapeutic potential due to their antioxidant and neuroprotective properties. These extracts also show promise as prebiotic agents. Further research is warranted to elucidate the underlying mechanisms and optimize their formulation for potential therapeutic applications in medicine and functional foods.

Cannabidiol-based Nanoformulations as Promising Drug Candidates Against Covid-19

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Background: The world is still facing a dramatic global health crisis related to the viral infection induced by SARS-CoV-2 that causes the disease COVID-19. Therefore, several strategies have been adopted to prevent, control and treat this virus, which still remains a challenge. The alternative to overcome this problem is the searching for new drug candidates. **Objectives:** Development of nanoformulations loading cannabidiol (CBD) with antiviral properties. **Methods:** Preparation of nanoformulations loading cannabis extract with different CBD concentrations. The resulting formulations were monitored in the physicochemical stability study in terms of size (nm), polydispersity index (PDI) and Zeta potential (mV), for 6 months (25 °C). The cytotoxicity and nanotoxicity assays were performed using VERO/Gammacoronavirus cell lines and chicken embryo model, respectively. **Results:** The nanoformulations showed excellent shelf time for 180 days at room temperature. Finally, it was determined the antiviral effective concentration and the safest CBD of the nanoformulations. **Conclusions:** The nanotechnological strategy proposed here described the development of biocompatible and efficient nanoformulations against COVID-19, providing promising candidates to be subjected to further preclinical studies.

Basic Science

Are seed hemp oils safe dietary supplements?

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Background: Hemp oils are growing in popularity as natural dietary supplements. Regulations on dietary supplements differ from country to country and region to region. Usually these products are treated as food and are not subject to strict testing and research ensuring their safety and quality. The lack of regulation of the psychoactive Δ 9-THC content in hemp oils does not guarantee the safety of such products. The limits set by European Commission (EU) Regulation 2023/915 are for maximum levels of total Δ 9-THC in hemp seed oil - 7.5 mg kg⁻¹ and in seeds and products derived from seeds - 3 mg kg⁻¹.

Objectives: The main objective of our study was to conduct a quantitative analysis of 17 selected cannabinoids, including those showing psychoactive effects (Δ 9-THC, Δ 8-THC and CBN), in hemp seed oils available on the Polish market. For this purpose, 27 hemp seed oil samples were analysed.

Methods: The liquid chromatography-Q-Exactive Orbitrap mass spectrometry technique operating with a heated electrospray interface (UPLC-HESI-MS/MS) was used for the analyses.

Results: On the basis of the analyses performed the permissible content of total Δ 9-THC was found to be exceeded in 22% of the samples, and in 56% of the samples the total Δ 9-THC content was less than the permissible limit. No Δ 8-THC was detected in the analyzed samples. The content of the 17 cannabinoids analysed in hemp oils ranged from 279-110,865 mg kg⁻¹.

Conclusion: Given the results obtained, it is appropriate to control the level of Δ 9-THC in hemp seed-based oils sold as dietary supplements.

Clinical Studies

Healthcare practitioners' self-experience when treating patients with cannabis in Israel

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Background: In Israel, cannabis is listed in 'The Dangerous Drug Ordinance' as a narcotic substance. Although there are tremendous numbers of published articles regarding cannabis, only a few published surveys have assessed the healthcare practitioners' self-experience when treating patients with cannabis – a "dangerous drug".

Objectives: The purpose of this study was to evaluate healthcare practitioners' self-experience when treating with cannabis.

Methods: A survey was conducted as an online questionnaire to physicians, pharmacists, and nurses who practice cannabis treatment. (cannabis healthcare practitioner – CHCP). It included 6 characteristic questions and 30 statements measured by Likert scale. Descriptive statistics and statistical analysis were made by ANOVA and Pearson Correlation via SPSS.

Results: Answers were collected between February 2022-March 2023. 75 participated, 76% completed. Among the general group of subjects, the majority agree there is difficulty in dealing with the medical/regulatory institution ($P=0.05$) and they do not feel antagonism toward their patients ($P=0.087$). Antagonism is mostly common among physicians, followed by nurses, and then pharmacists ($P=0.03$). Most satisfied are pharmacists, followed by nurses, and the least satisfied are doctors ($P=0.07$). CHCPs who use cannabis themselves, significantly believe more in the benefits of cannabis treatment ($P=0.036$). Although 68% stated they have the clinical knowledge to treat with cannabis, only 20% stated there is enough medical literature.

Conclusion: The study has found the most significant correlations between the type of profession and personal cannabis use with CHCP's self-experience when treating with cannabis. It seems that CHCPs rely on their clinical experience rather than evidence-based medicine when deciding on a treatment plan.

Clinical Studies

An analysis of clinical outcomes of medical cannabis therapy for pain conditions following at least 12 months of treatment

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Background: In November 2018, the UK rescheduled medical cannabis, allowing it to be prescribed as an unlicensed medicine for patients for whom licensed options have failed. Since then, between 25,000 and 30,000 patients have been prescribed medical cannabis. Among these patients, many will be seeking treatment for a pain condition.

Objectives: to assess the pain-specific and quality of life outcomes in patients received medical cannabis treatment in a UK medical cannabis clinic, following a minimum of 12 months of treatment.

Methods: a retrospective case series was performed. Patients whose primary condition was pain related, who had been receiving treatment at the clinic for a minimum of 12 months and who had completed both their initial and 12-month clinical evaluation were included.

Results: A total of 115 patients were included. Patients had been receiving treatment for approximately 2 years on average (25.89 months). Out of those patients, 20% (20.87%, n=24) were taking either an oil or a flower, while the rest were taking both (79.13%, n=91).

Significant improvements in baseline pain interference, baseline pain severity and quality of life were observed at 12 months (p0.05).

Conclusion: These results indicate that patients seeking medical cannabis for the treatment of a pain related condition experienced significant improvements at 12 months of treatment. Given that these patients will have had to attempt a minimum of two licensed options before being considered eligible for medical cannabis, this data suggests that medical cannabis may be an important option for pain patients and merits further study.

Clinical Studies

Effectiveness of cannabidiol and exercise for chemotherapy-induced peripheral neuropathy: preliminary results from the Cannex study

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Background: Chemotherapy-induced peripheral neuropathy (CIPN) remains challenging to manage clinically. In our observational study, cannabidiol (CBD) or an exercise program (EX) are provided to cancer survivors diagnosed with CIPN over a two months' period (phase-1). For patients who do not benefit sufficiently from either of the treatment's alone, CBD is combined with EX over another two months' period (phase-2).

Objective: To assess preliminary data on the effectiveness of CBD, EX or their combination to improve CIPN in cancer survivors.

Methods: Effectiveness is determined through the Functional Assessment of Cancer Therapy/Gynecologic Oncology Group-Neurotoxicity scale. A minimum clinically important difference (MCID) is set at a score improvement of 1.38-3.68 points. Very good responders, responders and non-responders are classified to have a score improvement above MCID, within the MCID range and unchanged/below the MCID, respectively.

Results: To date, 22 participants have completed phase-1; 14(64%) patients took CBD whereas eight(36%) patient did EX. Average age was 62.9+/-12.5 years and 81% were female. Cancer diagnoses included breast (36%), lymphoma (9%), ovarian (9%), uterine (9%), lung (9%), endometrial(5%), testicular(5%), pancreatic (5%), and head & neck (5%). After 8 weeks of CBD alone, eight (57%) participants were very good responders, two(14%) participants were responders, and four (29%) were non-responders. With EX alone, four (50%) were very good responders, one (13%) was a responder, and three(37%) patients were non-responders. Eight participants completed phase-2. With combination therapy, seven(88%) patients) were very good responders whereas only one (12%) patient did not respond.

Conclusion: Preliminary results suggest that EX and CBD in combination are more effective compared to their use as single agents in improving CIPN in cancer survivors.

Clinical Studies

Feasibility of a randomized, interventional pilot clinical study of oral cannabinoids in people living with HIV on ART: CTNPT 028

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Background: Cannabis-based medicines(CBM) could help reduce systemic inflammation in people with HIV(PWH). However, no clinical trials on CBM in PWH have been conducted in Canada. Between Sept 2021-Sept 2022, we aimed to recruit 26 PWH 18 years of age on ART for randomization to either cannabidiol(CBD) ± Δ9-tetrahydrocannabinol(THC) capsules, titrating doses as tolerated, for 12 weeks. The primary objective of this pilot study was to assess safety and tolerability(as previously reported). Here, we report on feasibility outcomes.

Objectives: To report on enrollment, compliance, and retention outcomes.

Methods: Ease of enrollment was based on consent rate. Compliance was assessed based on attendance at study visits. Retention was described as percentage of participants who remained in the study until the primary end point was reached. Verbal feedback was solicited from participants and study staff at close-out.

Results: Median age was 58(IQR 55-62); 80% were male. Consent rate was very low(5%; 10/205 persons approached). Recruitment of individuals approached was challenging due to 1)need for a cannabis washout period; 2)need to refrain from outside cannabis consumption; 3)stigma and 4)frequent study visits. Of 10 individuals randomized, 8(80%) completed the study; 2(20%) were withdrawn for safety reasons(transaminitis and aggravation of pre-existing anemia due to frequent blood draws). No participants missed scheduled visits and none dropped out voluntarily (100% compliance).

Conclusion: Recruitment was the most challenging aspect of conducting this study. Future studies should find a balance between requirements for safety monitoring and frequency of study visits. Ongoing work is required to reduce stigma related to CBM.

Clinical Studies

Efficacy and safety of cannabidiol followed by an open label add-on of tetrahydrocannabinol for the treatment of chronic pain in patients with inflammatory arthritis: concept and preliminary data.

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Background:

Rheumatoid arthritis (RA) and Ankylosing spondylitis (AS) are chronic, systemic, inflammatory diseases, primarily affecting the musculoskeletal system. Pain and fatigue are key symptoms of RA and AS.

Objectives

The present study aims to evaluate the efficacy and safety of add-on medical cannabis in the treatment of persistent pain in patients with RA and AS with low disease activity.

Methods:

A double-blinded, randomized, placebo-controlled study of cannabidiol (CBD), followed by an open label add-on of tetrahydrocannabinol (THC) in CBD non-responders with collection of clinical data and biological materials in RA and AS patients treated in routine care. Disease characteristics, psychological parameters, demographics, comorbidities, lifestyle factors, blood samples and serious adverse events are collected at baseline, after 12, 24 and 36 weeks.

Results:

Sixty-four patients were included. Due to the impact of the pandemic, the a priori estimated number of participating patients could not be reached. Serious side effects were not observed; low dose CBD and the combination of low dose THC and CBD was well tolerated. A clinical effect of Low dose CBD monotherapy was not detected. Results regarding the clinical effect of the combination of CBD and THC will be available in summer 2024.

Conclusions:

Chronic pain remains a major clinical problem in IA patients. In our study CBD and CBD/ THC low dose treatment was safe. CBD showed no clinical effect, data for the combination of low dose CBD and THC will be available in summer 2024.

Clinical Studies

Medical cannabis for chronic pain in the UK: a 12-month longitudinal observational study of 1721 individuals

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Background: Randomized controlled trials (RCT) have yielded conflicting evidence regarding cannabis-based products for medicinal use (CBPMs) in chronic pain. Trials are particularly hampered by heterogeneity in treatments and participants as well as recognised inter-individual variability in treatment dosing and response. There have been calls for greater consideration of real-world data (RWD) to assess treatment efficacy.

Objectives: To investigate real-world outcomes of CBPMs used for chronic pain.

Methods: Project Twenty21 is a UK initiative collecting RWD, incentivising participation via discounted access to certain CBPMs. We present 12-month outcomes from the 1721 individuals with chronic pain enrolled in the registry.

Results: The median age was 43, and 59% were male. 15% were cannabis-naïve, and this group were two-thirds female. Δ 9-tetrahydrocannabinol-dominant flower was the most prescribed treatment, followed by balanced oils. Among cannabis-naïve participants, balanced oils were the most prescribed. 1171 participants had at least one follow-up. Average pain interference, pain severity, sleep score, and quality of life were improved at all time-points vs baseline ($p < 0.05$), with scores plateauing after 6-months. 42% participants were considered “responders” (pain interference or severity 30% improved). Among responders, improvements in pain were sustained for 12-months. In the cannabis-naïve cohort, 36% participants were responders. Prescription opioid use was less prevalent during follow-up versus baseline, amounting to a 21.2% relative (9.8% absolute) reduction at 12-months ($p < 0.001$).

Conclusion: A substantial proportion of individuals with chronic pain may benefit from CBPMs, demonstrating reduced pain scores and prescription opioid use. 6-months may be the optimal trial duration to assess response, and benefits are generally durable among responders.

Clinical Studies

Full-spectrum cannabis extracts in the treatment of chronic pain patients

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Background Patients with chronic pain have a significantly reduced quality of life. They often suffer from depression and are no longer able to carry out their everyday tasks due to the pain and discomfort. Pain medicine is therefore looking for suitable therapies to break the vicious circle. **Objectives** Cannabis full-spectrum extract (tetrahydrocannabinol (THC)/ cannabidiol (CBD)) was administered. All 15 patients also received a multimodal treatment approach. The subject of the study was the treatment outcome and side effects. Treatment place was Waldhausklinik Deuringen (Acute Hospital for Internal Medicine, Pain Therapy, Complementary and Individualized Patient-centered Medicine, Germany). **Methods** To assess health related quality of life the Nottingham Health Profile (NHP) was used. The Patient Health Questionnaire (PHQ-D) was used to assess psychological well-being. Furthermore, daily blood pressure monitoring and measurement of pain intensity were carried out using a visual analogue scale (VAS). **Results** Patients had a high degree of chronicity of their pain. After an average therapy of 16.53 days, the pain intensity was reduced (6.36 to 4.7). Psychological impairment on admission (PHQ-D 15.46) could be significantly reduced by the time (PHQ-D 10.66). The patients` quality of life also improved without any significant side effects. There was no improvement in the dimensions of sleep and social isolation. **Conclusion** In the event of an acute exacerbation of chronic pain, the use of cannabis should also be considered, taking the accompanying illnesses into account. Further studies are important in order to be able to discuss a reduction in the use of strong opioids.

Clinical Studies

Aprepitant in Cannabis Hyperemesis Treated Intractable Vomiting Randomized Placebo Controlled Prospective Trial

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Background:

Cannabis is the most commonly used psychoactive substance in the U.S. besides alcohol and cigarettes. Aprepitant works by blocking one of the body's natural substances (neurokinin 1) that causes vomiting.

Methods:

In our study, 74 patients (age 27-56, BMI 19-21) smoked Cannabis for 10+ years, experiencing Cannabis hyperemesis syndrome were divided into three groups.

A: 30 received oral Aprepitant 125 mg the first day in ER and 80 mg for two days at home. Discharged the following morning.

3 patients admitted for 3 days inpatient.

B: 28 received IV Haloperidol 10 mg TID for 24 hours and was discharged from ER with oral Zofran 8 mg two days later.

5 patients were admitted for further management for 3 days.

C: 19 received IV Zofran 10 mg three times a day for 24 hours,

13 were admitted without symptom relief for 3 more days.

Result:

Group A 27 patients went home without hospitalization, GI or other subspecialty intervention. 90% Cure rate.

Group B 23 patients were discharged after 24 hours without GI or other Subspecialty intervention 82% cure rate.

Group C only 6 patients were discharged, 13 patients were admitted for 3 days, needing subspecialty intervention. GI, Renal 31.5% cure rate.

Conclusion:

Overall cost in hospital (Chest X-ray CT abdomen pelvis, inhospitable management and EGD) expenses in three groups were analyzed. Group A had significantly easier clinical profile and management with the most cost benefits ratio and hospital stay.