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Alzheimer Disease is a Neurological Condition that Causes Dementia

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Description

The Maximum Tolerated Dose (MTD), originally developed for systemic chemotherapies, is automatically selected for the Phase 3 confirmatory trial in oncology because dose-finding studies are typically carried out only in Phase I clinical trials. A paradigm shift is underway from the utilization of conventional MTD strategies to improved dose selection strategies for oncology programs with the introduction of anti-cancer therapies like immunotherapies and molecular targeted agents. To meet this new challenge, new study designs are required to maximize dose selection while still providing patients with life-altering new therapies as soon as possible. In this paper, we propose a two-in-one adaptive design that starts with a Phase 2 trial that evaluates multiple doses randomized and only selects one dose before moving on to a Phase 3 trial if an interim evaluation reveals evidence of efficacy. If multiple doses demonstrate promising efficacy, the lowest dose will be chosen, unless the higher dose demonstrates a stronger treatment effect. The study will seamlessly transition to a Phase 3 trial, with the chosen dose and patients enrolled in the Phase 2 portion serving as the basis for statistical inference in the Phase 3 portion. Under a moderate assumption, the overall Type I error can be controlled. The control of Type I error and the desirable operating characteristics of the proposed design are demonstrated through simulation studies.

Alzheimer's Disease

In today's oncology drug development, a Phase III pivotal trial can be immediately initiated when an experimental treatment exhibits a promising anti-tumor effect in Phase I efficacy expansion. The 2-in-1 design was proposed by Chen et al. to avoid skipping the traditional randomized Phase II Proof of Concept (POC) study. 2018) since its publication, this design has been expanded in numerous ways and has sparked a lot of interest in research and applications. One hypothesis in the Phase II portion and one hypothesis in the Phase III portion are controlled by the original 2-in-1 design's Family-Wise Type I Error Rate (FWER). However, in practice, the graphical approach controls the multiplicity for a standalone Phase III study with multiple hypotheses and group sequential interim analyses. When thinking about a 2-in-1 design, it would be ideal if these aspects of the Phase III design were preserved. In the literature, the Bonferroni method has primarily addressed the multiplicity control in Phase III for a 2-in-1 design with multiple hypotheses. While Jin and Zhang (2021) discussed the FWER control for a particular 2-in-1 design in which Phase II and Phase III have exactly the same hypotheses, the FWER control for a more common 2-in-1 design (one hypothesis in Phase II and multiple hypotheses in Phase III) is still under investigation for the more powerful graphical approach. The analytical conditions under which the graphical approach to controlling FWER in a 2-in-1 design are described in this paper. As would typically be the case with a direct Phase III design, it also offers numerical explorations of FWER control for such a design with group sequential interim analyses in Phase III. As a result, our work contributes to easing the way for the 2-in-1 design to be used in more applications. Alzheimer's disease (AD) is a neurological condition that causes dementia, also known as progressive memory loss and worsening of one's ability to think clearly. Although the exact cause of AD is unknown, it progresses with age and causes brain cells to gradually die over time. The World Health Organization (WHO) estimates that 50 million people worldwide suffer from dementia, with 60–70 percent of cases occurring in people with Alzheimer's disease (AD). Over the course of a few decades, accumulative research has demonstrated that investigational drugs that target a single target have limited efficacy because they are unable to treat complex diseases and do not provide a permanent cure. Planning of multi-target coordinated ligands (MTDLs) seems, by all accounts, to be more valuable and a sane way to deal with treat persistent complex illnesses including neurodegenerative infections.

Anti-Inflammatory

In recent years, medicinal chemists have conducted extensive research on MTDLs in order to create medications that can treat a variety of multifactorial diseases. Due to its neuroprotective, anti-inflammatory, anti-amyloid anti-aggregation, and antioxidant properties, Indole is one of the preferred scaffolds that is considered an essential mediator between the gut-brain axis. We have looked at the possibility that some indole-hybrids that act on multiple targets can play a role in the pathogenesis of AD. We highlighted the synthetic strategies, mechanisms of neuroprotection, toxicity, structure-activity relationships, and molecular docking studies of various indole-hybrid derivatives in a review of research articles from the years 2014–2021 from various scientific databases. According to the findings of this

literature review of published data on indole derivatives, the creation of indole hybrids has contributed to the creation of more potent compounds, prevented drug-drug interactions, improved the pharmacokinetic profile with lower toxicity, provided synergistic effect, and so on. Indole hybrids as MTDLs may play a significant role in the development of anti-AD molecules because of their demonstrated ability to inhibit multiple enzyme targets involved in the pathogenesis of AD.

A bento box model (3D-printed BB) with one or two chambers containing propranolol hydrochloride (PNL) powder and matrix tablets for controlled drug release at varying times in accordance with United States Pharmacopeia (USP) dissolution guidelines was the objective of this study. With varying infill percentages and wall thicknesses, the 3D-printed BBs were produced using commercial polyvinyl alcohol filament and a fused deposition modeling (FDM) 3D printer. A look at the appearance, thickness, size, weight, hardness, swelling, and erosion properties of the 3D-printed BBs was conducted. Using a FESEM, the surface and cross-sectional morphologies of the 3D-printed BBs were examined. The various infill percentages had a significant impact on the internal structure of the 3D-printed BBs' caps, but only a minor impact on the internal structure of their walls, as shown by FESEM images. The 3D-printed BB released PNL first in a pH 1.2 medium, then the drug in a pH 6.8 medium. The drug release percentage of some 3D-printed BB formulations may fall within all USP dissolution guidelines. As a result, 3D-printed BBs have the potential to change the pharmaceutical industry's future by making it easier to control the amount of drugs released at predetermined times.