Intranasal Delivery of Allopregnanolone

Tech ID: 34345 / UC Case 2019-565-0

ABSTRACT

Researchers at the University of California, Davis have developed non-invasive methods for intranasally delivering the drug allopregnanolone.

FULL DESCRIPTION

Allopregnanolone is a naturally produced, neuro-active steroid that has demonstrated its efficacy in the treatment of post-partum depression. Reduced levels of allopregnanolone in the peripheral blood or cerebrospinal fluid have also been linked to anxiety and mood disorders, as well as multiple neurological diseases. However, the physio-chemical properties of allopregnanolone pose a solubility challenge that limits its available administration methods. Consequently, allopregnanolone has been administered thus far primarily via parenteral routes of delivery - including intramuscular and intravenous methods. Currently, allopregnanolone is often administered via a 60-hour intravenous infusion under medical supervision. Parenteral administration increases treatment costs, is invasive and causes increased patient discomfort – along with corresponding declines in patient compliance. Thus, there is a need for non-invasive administration methods for allopregnanolone that can still deliver therapeutically relevant amounts of the drug to targeted sites in the body.

Researchers at the University of California, Davis have developed allopregnanolone compositions and related, drug administration methods to deliver the drug intranasally. Intranasal administration can deliver therapeutically meaningful levels of allopregnanolone directly to the brain, while reducing the potential side effect risks associated with systemic exposure. Additionally, this can also potentially circumvent poor gastrointestinal bioavailability and bypass the blood-brain barrier. This factor substantially differentiates intranasal delivery from other routes of administration.

Intranasal administration of allopregnanolone compositions led to a longer period of efficacy in an animal model, when compared with parenteral (e.g., intramuscular) administration, led to selective increased exposure of allopregnanolone in brain regions relevant to the therapeutic activity compared with the exposure in brain regions relevant to adverse-effects or toxicity. The researchers also found that intranasal allopregnanolone raises PTZ and bicuculline seizure thresholds and prolongs the time to occurrence of maximal PTZ-induced seizures. Thus, intranasal delivery is a feasible route of administration for allopregnanolone and can overcome the poor oral bioavailability of the neuroactive steroid.

APPLICATIONS

- Alternative delivery methods of allopregnanolone.

FEATURES/BENEFITS

- Non-invasive.
- Longer elapsed period of drug efficacy, thus reducing the required administration frequency.

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OTHER INFORMATION

KEYWORDS

non-invasive, non-parenteral, post-partum depression, anxiety, mood disorders, seizures, allopregnanolone

CATEGORIZED AS

- **Medical**
  - Delivery Systems
  - Disease: Central Nervous System
  - Disease: Women's Health
  - Therapeutics

RELATED CASES

2019-565-0

- Can be administered without oversight from specialized health care personnel or the use of medical facilities.

PATENT STATUS

Country	Type	Number	Dated	Case
United States Of America	Published Application	20220202832	06/30/2022	2019-565

ADDITIONAL TECHNOLOGIES BY THESE INVENTORS

- Edible Oils to Enhance the Absorption of Orally Administered Steroids Including Neurosteroids
- Cannabigerol (CBG) In The Treatment Of Seizures And Epilepsy

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