Webinar
Meniere`s Disease Update:2022

افق های جدید در درمان فارماکولوژیک بیماری مینیر

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گروه گوش و حلق و بینی

دانشگاه علوم پزشکی جندی شاپور اهواز

Selenium (Se)

- Selenium (Se) is an essential micronutrient for antioxidant defense that integrates an important part of selenoproteins. The most well-known selenoprotein is Glutathione peroxidase (GPx), which protects cells from damage caused by free radicals such as reactive oxygen species (ROS).
- Selenium blocks the activation of the nuclear transcription factor NFkB, a sensitive regulator that modulates the production of inflammatory mediators and adhesion molecules.

SPI-1005: Sound Pharmaceuticals

- SPI-1005 is an investigational new drug that contains **ebselen**, a novel small molecule that mimics and induces the activity of Glutathione Peroxidase (GPx) in the inner ear, retina, brain, lung, and kidney.
- SPI-1005 represents a novel class of anti-inflammatory and is under clinical investigation in several neurotologic diseases where GPx activity is reduced including sensorineural hearing loss, tinnitus, ototoxicity, Meniere's disease, and in neuropsychiatric disease including bipolar mania and treatment-resistant depression.
- SPI-1005 is entering pivotal **Phase 3** trials for the treatment of **Meniere's disease** and is currently in a Phase 2b study involving Cystic Fibrosis patients with acute respiratory infections receiving IV antibiotics.

SPI-1005

- The new drug to relieve the symptoms of tinnitus and sensorineural hearing loss in those with Meniere's disease is on the fast track in the new drug application process. The drug is called **SPI-1005** and is a product of the Sound Pharmaceuticals company
- SPI-1005 was dosed orally twice daily for 21 days and has demonstrated excellent safety and tolerability to date.
- In an earlier Phase 2 clinical trial, SPI-1005 was shown to prevent sensorineural hearing loss in young adults exposed to noise.
- The new drug, known as SPI-1005, boosts levels of a natural compound that protects delicate hair cells in the inner ear.

SPI-1005

- Ebselen is a small molecule mimic and inducer of glutathione peroxidase (GPx). GPx reduces reactive oxygen species by the binding of free radicals to its selenium moiety. Ebselen has strong anti-inflammatory characteristics.
- All subjects will undergo baseline audiometric testing and have their severity of sensorineural hearing loss, tinnitus and vertigo determined before the start of a 21-day course of treatment with SPI-1005
- 200mg SPI-1005 twice daily (BID)
- 400mg SPI-1005 BID

Famciclovir (Famvir)

- The specific aim of this study is to determine the efficacy of treatment with famciclovir in unilateral Meniere's Disease patients, specifically whether hearing can be improved.
- The investigators will determine the percentage of unilateral Meniere's Disease patients experiencing an absence of hearing fluctuation after 3 months of treatment with famciclovir as compared to the placebo arm.
- Patients will be instructed to take 250mg pills orally for the first 7 days (three times per day) at home. Patients will take a maintenance dose of one 250 mg pill twice a day for 77 days (11 weeks, total 3 months on drug).

Inclusion Criteria

- Unilateral Meniere's Disease
- 2 vertigo episodes of at least 20 minutes
- Fluctuating hearing by subjective history and/or audiometric documentation. Audiometric documentation is defined as affected ear pure-tone average change from an audiogram at Time 1 to Time 2 (less than one year apart) of greater than 15 dB.
- Less than 45 dB 4-frequency pure-tone average in the affected ear
- Tinnitus and/or aural fullness

Betahistine intranasal (AM-125)

- The intranasal delivery of AM-125 is intended to bypass the effects of first-pass metabolism found with oral delivery of betahistine. This is expected to offer significant additional benefits in terms of efficacy and tolerability.
- Betahistine is a small molecule drug that acts as a partial histamine H1-receptor agonist and a H3-receptor antagonist. The compound has demonstrated increased cochlear, vestibular and cerebral blood flow, vestibular compensation and the ability to inhibit neuronal firing in the vestibular nuclei. In the case of vertigo, the objective is to restore balance.
- AM-125 is currently in Phase II stage of development.
- Intranasal administration of betahistine has been shown to result in 6 to 29 times higher bioavailability.

Lamotrigine

- Lamotrigine will be taken orally on a daily basis for the duration of 20 weeks, consisting of a six-week titration(Possible doses for patients are 25mg twice a day, 50mg twice a day, 100 mg twice a day and 150mg twice a day during titration), 12-week study period(150mg twice a day or 100mg twice a day for the 12-week study period), and two-week taper(150mg once a day or 100mg once a day for Week 1 of the taper; and 75mg once a day, or 50mg once a day for Week 2 of the taper).
- Each increase in dose will be maintained for two weeks before deciding to further increase or decrease based on tolerability. Patients who discontinue at any point of the study will have a two-week taper consisting of the current dose once a day for one week followed by half the dose once a day for another week.

Latanoprost

- This drug, used for treatment of glaucoma, has been here tried in the ear. The apparent rationale is reduction of hydrops. This small study shows that it is feasible to use this drug.
- The authors report injections of this drug through the ear drum once/daily for 3 days. 9 patients were studied. They report improvements in vertigo (30%) and hearing.

Montelukast

- This is a double-blind, placebo-controlled randomized study aimed at proof of concept that montelukast, a previously FDA-approved medication that is known to help with allergy symptoms, may have efficacy in alleviating symptoms in patients with Meniere's Disease.
- For the duration of the study, subjects will be instructed to take one pill at night for 90 days.

Montelukast

Inclusion Criteria:

- Adults 18 years of age or older
- Must meet all AAO-HNS 2020 criteria for definite Meniere's Disease
- Must have a skin test positive for allergy. If subject does not have this previously documented, they will be asked to undergo allergy testing for skin test confirmation to at least one allergen.
- Is already a candidate for treatment with montelukast for allergic rhinitis/failed first line over-the-counter allergy treatments

Montelukast

Exclusion Criteria:

- Had a previous surgical procedure for treatment of vertigo
- Currently receiving any allergy immunotherapy or taking montelukast or a beta-blocker
- Pregnant or recent pregnancy (< 8 weeks postpartum, or lactation)
- Current hospitalization for any reason
- Any active, acute, or chronic pulmonary disorder other than asthma
- History of intubation for asthma

A clinical trial of a new investigational drug for vertigo in Ménière's disease -
Steroid-gel (OTO-104)

- The investigational product is given as a single injection into the middle ear through the eardrum. It is considered "investigational" because it has not been approved by the United States Food and Drug Administration (FDA) or another regulatory authority for treating Ménière's disease. The investigational product is being developed in hopes that it may relieve vertigo symptoms.
- This active investigational product will be compared to placebo, which is also given as an injection, but it has no active ingredients.
- Single Intratympanic Injection of 12 mg OTO-104 in Subjects With Unilateral Meniere's Disease

OTIVIDEX: Otonomy

- OTIVIDEX is a sustained-exposure formulation of the steroid dexamethasone. The drug is in clinical development for the treatment of Meniere's disease. OTIVIDEX has been granted Fast Track designation for Meniere's disease by the FDA.

OTONOMY™
Targeted Medicines for the Ear

Tolvaptan

- One hypothesis for the cause of Meniere's disease is excess body fluids in an inner ear compartment called the endolymphatic sac (ES). Currently, there are no treatments shown to reduce the fluid in the ES.
- To target the inner ear fluid regulation system in Meniere's patients, Dr. Grimes will repurpose an FDA approved drug that alters water homeostasis and is currently used to treat patients with low sodium levels.
- In this preclinical project, the research team will use a mouse model to determine if this repurposed drug has the potential to interrupt or lessen the frequency of Meniere's attacks. Positive results from this study would be the basis for clinical trials using aquaretics such as tolvaptan to improve the quality of life of Meniere's disease patients.

Diaoshi Jifa therapy

- Created by Dr. Diao, DiaoShi Jifa is a well-known traditional Chinese Medicine approach to treat dizziness in patients with chronic diseases. The investigators designed this randomized clinical trial to examine whether Diaoshi Jifa significantly decreases dizziness in patients with Meniere's disease.
- Change in Dizziness Handicap Inventory (DHI) Questionnaire Score [0 and 24 hours]dizziness Handicap Inventory (DHI) evaluates the self-perceived handicapping effects imposed by vestibular system disease.

Hyperbaric oxygen

- Fattori et al, Audiology 35(6):322-34, 1996. These authors report the results of treatment for 15 days with 90 min. sessions of a pressure chamber. They report better hearing results in the treated patients.

Labyrinth anesthesia

- (Adunka, Moustaklis et al. 2003) In this treatment, lidocaine and Kinetin are instilled into the middle ear using transtympanic injection.
- A remission was reported in 66% of patients. It is difficult to see why a local anesthetic that is gone in hours at most should cause a long lasting remission.
- Kinetin is a plant growth factor, pesticide, and an ingredient in skin preparations. Perhaps Kinetin has a positive effect on Meniere's disease.

APSLXR

- Clinical trial : 150 participants
- Multicentre, Open Label, Phase I Clinical Trial to Evaluate the Safety of APSLXR for the Treatment of Vertigo of Vestibular Origin or Meniere's Disease
- Age : 18-65
- Start day :July 2021
- Estimated Study Completion Date: October 2022

APSLXR

Inclusion Criteria:

- Diagnosis of Meniere's Disease or Vertigo of Vestibular Origin;
- Voluntarily consent to participate in the study;

Exclusion Criteria:

- Female patients who are pregnant or breastfeeding;
- Participants presenting uncontroled systolic hypertension (>140/90 mmHg);
- Participants presenting uncontroled diabetes (blood glucose >200 mg/dL).

ORB 202

- The goal of ORB-202 for human use is to deliver 10 mg of steroid in a 200 µL injection volume through an 88.9 mm 26 GA needle, with less than 50% of the dose free for immediate therapeutic relief, and at least 50% of the dose available for sustained release.
- The current investigation describes development of the platform fostering ORB-202 and the associated in vitro and in vivo characterization of the platform.

Antifungals

- Leong et al recently published a retrospective study of 26 patients treated with oral **mycostatin**, an antifungal.
- This is an uncontrolled study, and subject to the usual problems of these studies in Meniere's disease (Leong, Pothie, Rutka 2014). While "hope springs eternal", this is pretty thin data.
- It is difficult to see why an antifungal that is confined to the intestinal tract would be helpful for Meniere's disease.
- Neely and Nelson published a similar paper in 1994.

Water

- In an amazing report, Naganuma and others from Japan (2006) studied 29 people and reported that large amounts of water intake taken over 2 years (35 ml/Kg -- or about 2.5 liters for a 70 kilo person), "dramatically relieved vertigo" and significantly improved hearing in the last 6 months

Prochlorperazine

- For vertigo and Meniere's disease, prescribe prochlorperazine 5 mg orally three times a day (maximum dose 30 mg daily
- Prochlorperazine is an anti-sickness medicine. It can help stop you feeling or being sick (nausea or vomiting).
- Prochlorperazine tablets and liquid are available on prescription
- Prochlorperazine starts to work in around 30 to 60 minutes.
- Prochlorperazine is a type of medicine called a phenothiazine. It works by blocking dopamine receptors in the brain. Dopamine is a natural compound called a neurotransmitter that is involved in transmitting messages between brain cells. It's known to be involved in regulating mood and behaviour. It also acts in an area of the brain that controls nausea and vomiting.

prochlorperazine

- You can take prochlorperazine to treat:
- morning sickness
- feelings of dizziness (vertigo)
- travel sickness
- feelings of sickness due to migraines
- sickness caused by general anaesthetics after surgery, cancer treatment or taking other medicines
- problems with balance such as Ménière's disease
- Prochlorperazine may occasionally be used to treat some forms of anxiety

سامانه ثبت بیماران مِینیِر خوزستان

تعداد ثبت نام در سامانه

از مهر ماه سال ۱۳۹۸

زن	مرد	
۱۸	۲۵	تعداد
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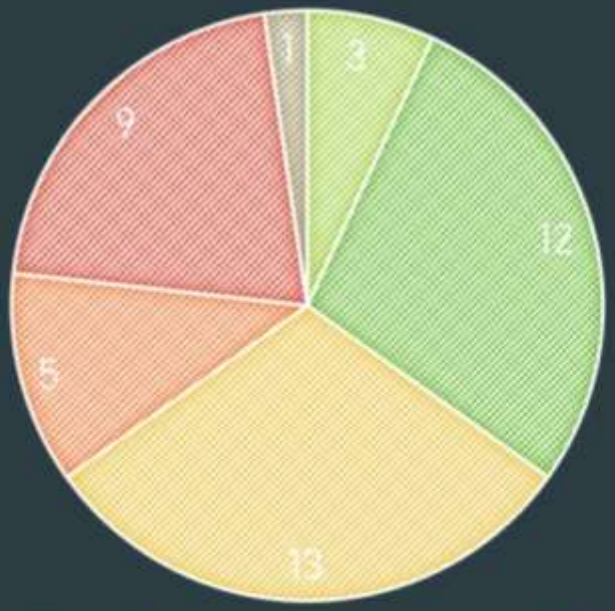
تعداد بر اساس
محدوده سنی



میانگین سنی = ۴۷

مشکلات سامانه

- فیلد آدرس در فرم فیزیکی وجود نداره که برای پیگیری ضروری است.
- در قسمت علائم ماژور عنوان گزینه دوم در فرم فیزیکی و سامانه متفاوت است.
- در قسمت علائم ماژور (سرگیجه یا احساس گیجی و سبکی سر) در سامانه نیست.
- در قسمت علائم ماژور (شنوایی) عنوان نوع تن بهتر است مانند فرم فیزیکی از عنوان فرکانس استفاده شود. همچنین گزینه های انتخابی این فیلد.
- در قسمت نتیجه ECoG با انتخاب گزینه ندارد فیلد مرتبط با آن غیر فعال نمی گردد.
- اگر برای هر فرد کد شناسه تعریف بشه خیلی بهتره