ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 09/15/2015

Safety and Feasibility Study of Intranasal Mesenchymal Trophic Factor (MTF) for Treatment of Asthma

This study is currently recruiting participants.
Verified by Translational Biosciences, September 2015

Sponsor:	Translational Biosciences
Collaborators:	
Information provided by (Responsible Party):	Translational Biosciences
ClinicalTrials.gov Identifier:	NCT02192736

Purpose

Allogeneic mesenchymal trophic factors (MTF) from human umbilical cord tissue-derived mesenchymal stem cells (UC-MSC) administered intra-nasally to 20 patients is a safe and useful procedure for inducing improvements in pulmonary function and quality of life in asthma patients.

Condition	Intervention	Phase
Asthma	Biological/Vaccine: Trophic factors from umbilical cord mesenchymal stem cells	Phase 1/ Phase 2

Study Type: Interventional
Study Design: Treatment, Single Group Assignment, Open Label, N/A, Safety/Efficacy Study
Official Title: Safety and Feasibility Study of Intranasal Mesenchymal Trophic Factor (MTF) for Treatment of Asthma

Further study details as provided by Translational Biosciences:

Primary Outcome Measure:

- Number of patients with adverse events [Time Frame: 1 month] [Designated as safety issue: Yes]
  Evaluated 1 month after the final treatment

Secondary Outcome Measures:

- Number of patients with a change in pulmonary function from baseline as measured by Forced Expiratory Volume (FEV1) following American Thoracic Society (ATS) guidelines [Time Frame: a) 1 week, 2 weeks, 3 weeks, 4 weeks b) 1 month] [Designated as safety issue: No]
  a. After first treatment
  b. After final treatment
- Number of patients with a change in pulmonary function from baseline as measured by Forced Vital Capacity (FVC) following American Thoracic Society (ATS) guidelines [Time Frame: a) 1 week, 2 weeks, 3 weeks, 4 weeks b) 1 monrh] [Designated as safety issue: No]
  a. After first treatment
  b. After final treatment

- Number of patients with a change in quality of life from baseline as measured by the University of Pittsburgh Medical Center (UPMC) Asthma Questionnaire [Time Frame: a) 1 week, 2 weeks, 3 weeks, 4 weeks b) 1 month] [Designated as safety issue: No]
    a. After first treatment
    b. After last treatment

Estimated Enrollment: 20
Study Start Date: July 2014
Estimated Primary Completion Date: June 2016
Estimated Study Completion Date: December 2016

Arms	Assigned Interventions
Intra-nasal infusion of MTF Trophic factors from umbilical cord mesenchymal stem cells administered intra-nasally	Biological/Vaccine: Trophic factors from umbilical cord mesenchymal stem cells

Detailed Description:

The proposed study will assess primary safety and secondary efficacy endpoints of allogeneic UC-MSC-derived MTF administered to asthma patients. Each patient will receive intra-nasal MTF once per week for a period of 4 weeks.

Eligibility

Ages Eligible for Study: 21 Years to 60 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Signed consent form by the subject
- Male or female
- Between 18 and 65 years old and capability to comprehend this trial.
- Asthma diagnosed by a physician at least 1 year prior to study enrollment
- Poorly-controlled asthma at study enrollment. Poorly controlled asthma is defined as: chronic symptoms, episodic exacerbations, persistent and variable airways obstruction despite a continued requirement for short-acting beta 2-agonists despite the use of high doses of inhaled steroids.
- Nonsmokers (stopped smoking at least 1 year ago) and limited life-time history of smoking (less than a 3 pack year history).
- Body mass index 19-40
- On a stable dose of inhaled corticosteroid for at least 4 weeks prior to study entry or had to use a rescue dose during the last 4 weeks.
- FEV1 >50% predicted

Exclusion Criteria:

- Pregnant or lactating women
- Cognitively impaired adults
- Systemic steroids within the 4 weeks prior to enrollment
- Non-steroidal anti-inflammatory drugs (NSAIDs) for arthritis
- Current diagnosis of polyposis or sinusitis.
- Infection treated by antibiotics within the 4 weeks prior to enrollment
- Immunization within the 4 weeks prior to enrollment
- Lung pathology other than asthma
- Other significant non-pulmonary co-morbidities such as: coronary artery disease, peripheral vascular disease, cerebrovascular disease, congestive heart failure with an ejection fraction <50%, liver disease or

elevated liver enzymes at baseline, malignancy (excluding non-melanoma skin cancers), AIDS, renal failure with serum creatinine >3.0, or disorders requiring steroid treatment such as vasculitis, lupus, rheumatoid arthritis
- Illicit drug use within the past year
- Current/active upper respiratory infection (URI) (if active URI, wait until asymptomatic for 1 week to enroll)
- Asthma exacerbation within the 4 weeks prior to enrollment (includes ER, urgent care, or hospital visits due to asthma resulting in an increase in asthma-related medications)
- Undergoing evaluation for sleep apnea, or plans to institute treatment for sleep apnea (patients on a stable treatment regimen for sleep apnea for the last 3 months prior to enrollment will be allowed to participate)
- Clinically significant abnormalities present on screening 12-lead electrocardiogram
- Women of childbearing potential using oral contraceptives who are not willing to use a second method of contraception during the study
- Participation in another clinical study within 4 weeks prior to enrollment
- Subject does not sign informed consent

Contacts and Locations

Contacts

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Locations

Panama

Punta Pacifica Hospital — Recruiting

Panama City, Panama

Investigators

Principal Investigator:	Moises Zebede, MD	Punta Pacifia Hospital in Panama City, Panama

More Information

Responsible Party:	Translational Biosciences
Study ID Numbers:	TBS-MTFAS-001
Health Authority:	Panama: Ministry of Health