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

This study is currently recruiting participants. (see Contacts and Locations)

Verified July 2014 by *Translational Biosciences*

Sponsor:
Translational Biosciences

Information provided by (Responsible Party):
Translational Biosciences

ClinicalTrials.gov Identifier:
NCT02192736

First received: July 14, 2014
Last updated: July 15, 2014
Last verified: July 2014
History of Changes

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: Trophic factors from umbilical cord mesenchymal stem cells	Phase 1 Phase 2

Study Type: Interventional
Study Design: Endpoint Classification: Safety/Efficacy Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

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

Resource links provided by NLM:

MedlinePlus related topics: Asthma

U.S. FDA Resources

Further study details as provided by Translational Biosciences:

Primary Outcome Measures:

- 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 Study Completion Date:	December 2015
Estimated Primary Completion Date:	June 2015 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Intra-nasal infusion of MTF Trophic factors from umbilical cord mesenchymal stem cells administered intra-nasally	Biological: 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 21 and 60 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 19-31
- On a stable dose of inhaled corticosteroid for at least 4 weeks prior to study entry
- 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

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02192736

Contacts

Contact: Marggie Arosemena +507 306-2600 trials@translationalbiosciences.com

Locations

Panama

Punta Pacifica Hospital **Recruiting**
Panama City, Panama

Sponsors and Collaborators

Translational Biosciences

Investigators

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

More Information

No publications provided

Responsible Party:	Translational Biosciences
ClinicalTrials.gov Identifier:	NCT02192736 History of Changes
Other Study ID Numbers:	TBS-MTFAS-001
Study First Received:	July 14, 2014

Last Updated: July 15, 2014
Health Authority: Panama: Ministry of Health

Keywords provided by Translational Biosciences:
asthma
umbilical cord
mesenchymal
stem cells
trophic factors

Additional relevant MeSH terms:
Asthma
Bronchial Diseases
Respiratory Tract Diseases
Lung Diseases, Obstructive
Lung Diseases
Respiratory Hypersensitivity
Hypersensitivity, Immediate
Hypersensitivity
Immune System Diseases

ClinicalTrials.gov processed this record on July 16, 2014

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