Association of Beta-2 Adrenergic Agonist and Corticosteroid Injection in the Treatment of Lipomas

A Pilot Study: Association of Beta-2 Adrenergic Agonist and Corticosteroid Injection in the Treatment of Lipomas

Sponsors	**Lead Sponsor:** Pennington Biomedical Research Center **Collaborator:** Lipothera
Source	Pennington Biomedical Research Center
Brief Summary	The purpose of this study is to test whether injected medications will increase the amount of fat released by a fat cell. We will compare prednisolone (a synthetic cortisone) combined with isoproterenol (a drug given for asthma) versus using isoproterenol alone. We will also test if injections of isoproterenol and prednisolone will shrink the size of lipomas, which are benign fatty tumors.
Detailed Description	Lipomas are benign, non-cancerous fatty tumors that occur under the skin and make a bump that can be easily felt and often seen. The current treatment for lipomas is surgery. Isoproterenol, a medication used for the treatment of asthma and approved for injection under the skin, is known to cause fat cells to give up their fat. The fat cells become resistant to isoproterenol with repeated use. Prednisolone, a synthetic cortisone medication used to treat immune problems like allergy and approved for injection under the skin, keeps the fat cells from becoming resistant to isoproterenol. It is not known, if the fat cells in lipomas act like other fat cells or if the combination of isoproterenol and prednisolone injections would shrink lipomas without surgery. This study is designed to test this possibility. Subjects will have a screening visit, 2 microdialysis visits a week apart, 20 treatment visits 5 days per week for 4 weeks, and up to 12 follow-up visits a year after treatment visits. During screening, subjects will have a history, physical exam, blood testing, electrocardiogram and a pregnancy testing if female with reproductive capacity. The first microdialysis visit will consist of placing two microdialysis catheters under the skin after the area is numbed. One microdialysis catheter will be in the lipoma and the other under the skin 2 inches away. The microdialysis catheter will connect to a pump, isoproterenol will be infused and the amount of fat breakdown measured. One week later prednisolone will be injected into the lipoma and under the skin 2 inches away. The microdialysis visit will be repeated 24 hours later. Treatment will consist of injecting the lipoma 5 days a week with a mixture of isoproterenol and prednisolone in the Pennington clinic as a diabetic would inject insulin. Each week the blood pressure, pulse and lipoma will be

measured and subjects will be asked how they feel. At the end of the treatment period the physical examination, blood test and electrocardiogram will be repeated.

The insertion of the microdialysis probes under the skin into the fat tissue could be uncomfortable, but numbing medication will be injected first to prevent this problem. At higher doses, isoproterenol could lower blood pressure and increase pulse rate. This should not happen at the doses used, but blood pressure and pulse will be monitored throughout the study. Prednisolone, at higher doses, could decrease the body's production of cortisone. This should not happen at the doses being used, but cortisone in the body will be measured during the trial. Blood tests involve the discomfort of a needle going through the skin of the arm, possible bruising and rarely fainting or infection. Trained technicians and sterile needles will minimize these risks.

Overall Status	Completed	
Start Date	October 2007	
Completion Date	March 2009	
Primary Completion Date	March 2009	
Phase	Phase 1/Phase 2	
Study Type	Interventional	
Primary Outcome	Measure	Time Frame
	The Average Percent Volume Reduction in the Lipoma.	Baseline and 4 weeks
Secondary Outcome	Measure	Time Frame
	The Number of Lipoma Increased in Volume.	After four weeks of treatment up to one year.
	The Number of Subjects Elected to Have the Lipoma Removed.	After four weeks up to one year.
Enrollment	10	

Condition	• Lipoma
Intervention	**Intervention Type:** Drug **Intervention Name:** Prednisolone synthetic cortisone and Isoproterenol together **Description:** Approximately 0.2 to 0.4cc of isoproterenol-prednisolone solution (0.04 - 0.08 mg isoproterenol and 0.07 - 0.14 mg prednisolone) in one or more sites in the lipoma depending on its size, 5 days a week for 4 weeks. **Arm Group Label:** Prednisolone and Isoproteronol Together **Other Name:** Prednisolone combined with Isoproterenol
Eligibility	**Criteria:**

Drug Interventions

Annexin A5
Anti-Ulcer Agents
Antimony Sodium Gluconate
Cromolyn Sodium
Dexamethasone, neomycin, polymyxin B drug combination
Flax
Frovatriptan
Histidine
Interferon-beta
Letrozole
Lornoxicam
Natriuretic Peptide, Brain
Zidovudine

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Conditions

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Alphabetic (A-Z)

Drug Interventions

Alphabetic (A-Z)
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By Category

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Inclusion Criteria:

- You are a man or a woman between the ages of 18-60, inclusive.

- You have a body mass index (BMI) between 20 and less than 40 kg/m2. BMI is a number calculated from your height and weight.

- You have a lipoma (a benign fatty tumor) that is 1 inch or more in diameter under the skin of your abdomen or on another area of your body that is easily accessible to study (such as the thigh).

- You have not gained or lost more than 11 pounds in the last 3 months.

- Your exercise routine has been stable for the last 3 months or you are sedentary. Sedentary means you do less than 60 minutes of exercise per week.

Exclusion Criteria:

- You have a history of heart or blood vessel disease.

- Your blood pressure is above 140/90 mmHg.

- You have type 1 diabetes.

- You have a history of kidney or liver disease.

- You have thyroid disease that has not been treated.

- You are a smoker.

- You use a Beta-2 (B2) adrenergic stimulator (a type of drug used to treat asthma), a beta adrenergic blocker (a type of drug used to treat blood pressure) or glucocorticoid medications (a type of drug used to treat immune system disease).

- You have a problem with alcoholism or other substance abuse.

- You are pregnant or breast feeding.

Gender: All

Minimum Age: 18 Years

Maximum Age: 60 Years

Healthy Volunteers: Accepts Healthy Volunteers

Overall Official		
Location	Facility:	Pennington Biomedical Research Center
Location Countries	United States	
Verification	December 2015	

Date	
Responsible Party	**Type:** Principal Investigator **Investigator Affiliation:** Pennington Biomedical Research Center **Investigator Full Name:** Frank Greenway **Investigator Title:** Principal Investigator
Keywords	• Obesity therapy • fat • drug mechanism • adipose tissue • cellular pharmacology
Has Expanded Access	No
Condition Browse	• Lipoma
Number Of Arms	1
Arm Group	**Label:** Prednisolone and Isoproteronol Together **Type:** Other **Description:** Beta-adrenergic agonists and corticosteroid
Study Design Info	**Allocation:** Non-Randomized **Intervention Model:** Single Group Assignment **Primary Purpose:** Treatment **Masking:** None (Open Label)

Source: ClinicalTrials.gov

Medical Conditions

Airway Obstruction
Carotid-Cavernous Sinus Fistula
Chandler's Syndrome
Fournier Gangrene
Hereditary Sensory and Motor Neuropathy
Neoplasms, Nerve Tissue
Neoplastic Syndromes, Hereditary
Polyarteritis Nodosa
Popliteal Cyst
Spinal Muscular Atrophy With Respiratory Distress 1
Spinal Stenosis
Typhus, Epidemic Louse-Borne
Vitreous Hemorrhage

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Sponsors and Collaborators

American Lung Association Asthma Clinical Research Centers
Arla Foods
Children's Memorial Health Institute, Poland
Conselho Nacional de Desenvolvimento Cientifico e Tecnologico
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