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Therapeutic Treatment With Human Papillomavirus Quadrivalent Vaccine for Recurrent Respiratory Papillomatosis

This study is enrolling participants by invitation only.

First Received: January 5, 2009 Last Updated: January 26, 2009 [History of Changes](#)

Sponsor:	University of Missouri-Columbia
Information provided by:	University of Missouri-Columbia
ClinicalTrials.gov Identifier:	NCT00829608

Purpose

The purpose of this study is to determine if administration of the HPV quadrivalent vaccine in patients diagnosed with RRP has a therapeutic effect on their clinical course. More specifically, does administration of the vaccine decrease the size and number of papillomas, severity of disease (i.e. hoarseness, inspiratory vs. biphasic stridor, airway obstruction) using the LCAS and time interval between required surgical debulking will be analyzed.

Condition	Intervention	Phase
Recurrent Respiratory Papillomatosis	Biological: Human Papillomavirus Quadrivalent Vaccine	Phase 0

Study Type: Interventional

Study Design: Allocation: Non-Randomized

Control: Uncontrolled

Endpoint Classification: Safety/Efficacy Study

Intervention Model: Single Group Assignment

Masking: Open Label

Primary Purpose: Treatment

Official Title: Investigator Initiated Study of Effects of Progression of Recurrent Respiratory Papillomatosis in Patients After They Are Given Human Papillomavirus Quadrivalent Vaccine

Resource links provided by NLM:

[MedlinePlus](#) related topics: [Surgery](#)

[U.S. FDA Resources](#)

Further study details as provided by University of Missouri-Columbia:

Primary Outcome Measures:

- Comparison of the pre-vaccine and post-vaccine RRP scoring assessments, intersurgical intervals, and annualized surgical rates. [Time Frame: 12 months]
[Designated as safety issue: Yes]

Secondary Outcome Measures:

- The secondary end points will include changes in the RRP scoring assessment, intersurgical intervals and changes in annualized surgical rates. [Time Frame: 12 months]
[Designated as safety issue: No]

Estimated Enrollment: 10

Study Start Date: January 2009

Estimated Study Completion Date: June 2010

Estimated Primary Completion Date: December 2009 (Final data collection date for primary outcome measure)

<u>Arms</u>	<u>Assigned Interventions</u>
<p>Patients diagnosed with RRP: Experimental There are 9 participants currently being followed in the faculty sponsor's clinic that carry the clinical and histologic diagnosis of RRP. The 9 participants meet one or more of the following criteria: Surgery requirement of more than 4 procedures per year, distal multisite spread of disease, and rapid regrowth of papilloma disease with airway compromise.</p>	<p>Biological: Human Papillomavirus Quadrivalent Vaccine 0.5 mL of quadrivalent HPV vaccine will be given intramuscularly at three separate intervals. Dose 2 is given 2 weeks after dose 1 and dose 3 is given 4 weeks after dose 1 for a total of 3 doses over 2 months.</p>

Detailed Description:

Patients who carry the diagnosis of Recurrent Respiratory Papillomatosis (RRP) will be asked to participate in the study. These patients have been followed by the faculty investigator for several years. Their disease state requires frequent interventions aimed at decreasing the severity and symptomatology of their vocal fold papillomas. Patients will be given the human papillomavirus quadrivalent vaccine and their clinical course will be followed over the next 6 months. Patients will have a laryngoscopic examination prior to treatment to establish their baseline disease state. They will have repeat laryngoscopic examinations at the time of the first, second and third vaccine injections, which will be given 1 month intervals for a total of 3 doses. They will have physical exam and laryngoscopic examinations at 1 month intervals for the first 6 months after administration of the vaccine. The severity of their clinical disease will be objectively measured using a validated scale for RRP assessment, the Laryngoscopic and Clinical Assessment Scale (LCAS).

Eligibility

Ages Eligible for Study: 18 Years to 80 Years
Genders Eligible for Study: Both

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- There are 9 participants currently being followed in the faculty sponsor's clinic that carry the clinical and histologic diagnosis of RRP. The 9 participants meet one or more of the following criteria: Surgery requirement of more than 4 procedures per year, distal multisite spread of disease, and rapid regrowth of papilloma disease with airway compromise.

Exclusion Criteria:

- If any of the 9 patients meet the following criteria they will be excluded from the study:
 - Pregnancy
 - Hypersensitivity or allergy to vaccine components (i.e. Saccharomyces cerevisiae yeast)
 - Immunocompromised patients (i.e. patients with HIV, cancer, or who take immunosuppressant medications including all forms of steroids)
 - Have a fever over 100°F (37.8°C)
 - Moderate or severe acute illness (with or without fever)
 - Coagulopathies
 - Platelet counts of less than 100,000
 - Any history of recent treatment (within 3 months) with any investigational drug or other adjuvant RRP therapy (including interferon-gamma, ribavirin, acyclovir, cidofovir and photodynamic therapy, indole-3-carbinol)

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00829608

Locations

United States, Missouri

University of Missouri

Columbia, Missouri, United States, 65212

Sponsors and Collaborators

University of Missouri-Columbia

Investigators

Principal Investigator: Troy D Scheidt, MD University of Missouri-Columbia

▶ More Information

No publications provided

Responsible Party: University of Missouri - Columbia (Troy D. Scheidt, M.D.)

ClinicalTrials.gov Identifier: [NCT00829608](#) [History of Changes](#)

Other Study ID Numbers: 1124197

Study First Received: January 5, 2009

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Health Authority: United States: Institutional Review Board

Keywords provided by University of Missouri-Columbia:

RRP

Recurrent Respiratory Papillomatosis

HPV vaccine

HPV

Additional relevant MeSH terms:

Neoplasms

Neoplasms by Histologic Type

Neoplasms, Squamous Cell

Papilloma

Neoplasms, Glandular and Epithelial

ClinicalTrials.gov processed this record on May 23, 2010

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