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A comparison of bone-anchored sutures and radiofrequency energy for treatment of lateral wall collapse causing nasal obstruction.

Submission date
17/12/2014

Recruitment status
No longer recruiting

Registration date
12/01/2015

Overall study status
Completed

Last Edited
02/02/2015

Condition category
Ear, Nose and Throat

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Lateral nasal wall collapse (collapse of the side of the nose) can cause nasal congestion. The side of the nose (nasal sidewall) collapses due to negative pressure and structural weaknesses of the nose. Bone anchored suture suspension is a technique used by many surgeons to treat it. It involves anchoring the nasal sidewall to the bony rim below the eye. A recently described technique involves treating the soft tissue of the side of the nose with radiofrequency heat to create a scar that makes the tissue firmer. We want to compare the two treatments to each other. We hope to determine how well the new technique performs in managing lateral nasal wall collapse when compared to one of the standard surgical treatments and also non- surgical treatments. This knowledge could change surgical management as radiofrequency thermotherapy is less invasive, could be performed with only local anesthesia, and does not involve implants - in contrast to the more established bone anchored suture suspension.

Who can participate?
Adults (aged over 18) with nasal obstruction (blockage).

What does the study involve?
Participants are randomly allocated into one of three groups. Those in group 1 are treated using radiofrequency thermotherapy. Those in group 2 are treated using the conventional bone anchored suture suspension technique. Those in group 3 are given non-operative treatments. All patients are assessed for lateral wall insufficiency, nasal obstruction and pain caused by the nasal obstruction before and after treatment.

What are the possible benefits and risks of participating?
Radiofrequency thermotherapy of the lateral nasal wall is a new technique, but radiofrequency treatment itself is well established in the field of otolaryngology (ear, nose and throat specialists) to treat conditions such sleep apnea and other causes of nasal obstruction. Known risks include excess thermal (heat) damage and pain.

Where is the study run from?
Stanford University (USA)

When is the study starting and how long is it expected to run for?
February 2010 to February 2012

Who is funding the study?
1. Stanford University (USA)
2. American Academy of Facial Plastic & Reconstructive Surgery (USA)

Who is the main contact?
Dr Sam Most

Contact information

Type(s)
Scientific

Contact name
Dr Sam Most

Contact details
801 Welch Road
Stanford
United States of America
94305

Additional identifiers

Protocol serial number
IRB-18115

Study information

Scientific Title
Treatment of lateral nasal wall collapse - a comparison of Bone Anchored SuTure suspension versus Radiofrequency Thermotherapy.

Acronym
BAST vs RF

Study objectives
Our hypothesis is that RF will work as well as bone-anchored sutures in treatment of lateral wall insufficiency (LWI).

Ethics approval required
Old ethics approval format

Ethics approval(s)

Stanford Human Subjects, 2/3/2010, ref: IRB-18115

Study design
This is a single-center, randomized, interventional trial comparing two techniques for treatment of lateral wall insufficiency.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Lateral nasal wall collapse is a source of nasal congestion which plagues many people as the sidewall of the nose collapses due to negative pressure and structural weaknesses of the nose.

Interventions
Bone anchored suture suspension is used by many surgeons to treat lateral wall insufficiency, and involves anchoring the nasal sidewall to the bony rim below the eye. A recently described technique involves treating the sidewall soft tissue with radiofrequency heat to cause scar contraction of the tissue to minimize laxity. We will compare the two treatments to each other, and to non-operative treatment of otherwise surgically-eligible candidates.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Clinician-derived measure of lateral wall insufficiency (LWI score).
2. NOSE (nasal obstruction symptoms evaluation)

Measured at preoperative and postoperative visits.

Key secondary outcome(s))
1. Visual analog scale for nasal obstruction (VAS)

Measured at preoperative and postoperative visits.

Completion date
28/02/2012

Eligibility

Key inclusion criteria
1. Healthy adults with nasal obstruction
2. Over age 18
3. Either gender
4. Any ethnic background

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Children
2. Pregnant women

Date of first enrolment
01/02/2010

Date of final enrolment
28/02/2012

Locations

Countries of recruitment
United States of America

Study participating centre
Stanford University
United States of America

Sponsor information

Organisation
Stanford University Department of Otolaryngology

ROR
https://ror.org/00f54p054

Funder(s)

Funder type
University/education

Funder Name
Stanford University

Alternative Name(s)
Stanford, Leland Stanford Junior University, SU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United States of America

Funder Name
Educational and Research Foundation for the American Academy of Facial Plastic and Reconstructive Surgery

Alternative Name(s)
AAFPRS Foundation, Educational & Research Foundation for the American Academy of Facial Plastic and Reconstructive Surgery, Educational and Research Foundation for the American Academy of Facial, AAFPRS Foundation; Educational & Research Foundation for the American Academy of Facial Plastic and Reconstructive Surgery, AMERICAN ACADEMY OF FACIAL PLASTIC AND RECONSTRUCTIVE SURGERY, INC., AAFPRS

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2015		Yes	No