A Prospective Study of RejuvenAir* System Radial Spray Cryotherapy to Determine Safety and Histological Effect in the Lung

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The study objective is to demonstrate the feasibility and safety (measured by the occurrence of serious adverse events) of the RejuvenAir System Radial Spray Cryotherapy in a population of subjects who are scheduled to undergo a planned lobectomy or…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders NEC
Study type	Interventional

Summary

ID

NL-OMON40702

Source
ToetsingOnline

Brief title
RejuvenAir* System Lobectomy

Condition

- Respiratory disorders NEC

Synonym
COPD

Research involving
Human

Sponsors and support

Primary sponsor: CSA Medical Inc.

Source(s) of monetary or material Support: CSA medical

Intervention

Keyword: COPD, Cryotherapy, lobectomy

Outcome measures

Primary outcome

Safety as measured by occurrence of serious adverse events related to metered dose radial spray cryotherapy treatment performed prior to scheduled lobectomy or pneumonectomy surgery

Secondary outcome

Description of tissue depth effect per specified dose using routine tissue staining.

Study description

Background summary

Cryotherapy results in cell destruction while leaving the extracellular matrix of the treated tissue intact. There is extensive human experience with cryotherapy to date, including use in the airways. CSA is developing the RejuvenAir* System, which is a modified delivery system based on its FDA cleared truFreeze® System to address less localized surface areas of the airways in order to treat chronic bronchitis. The purpose of this open label, single arm study is to demonstrate the feasibility and safety of the RejuvenAir System powered by truFreeze Technology, in Subjects who are scheduled to undergo lobectomy, and to understand the histological characteristics and healing outcomes in the airways in humans. This study is expected to lead to a study in Subjects with chronic bronchitis.

Study objective

The study objective is to demonstrate the feasibility and safety (measured by the occurrence of serious adverse events) of the RejuvenAir System Radial Spray Cryotherapy in a population of subjects who are scheduled to undergo a planned lobectomy or pneumonectomy. A secondary objective is the description of tissue

depth effect per specified dose using routine tissue staining.

Study design

Prospective, open label, single arm, multicenter study

Intervention

Surgical lobectomy or pneumonectomy will proceed as clinically planned. On the day of scheduled surgery, Subject will undergo, prior to te surgery, the bronchoscopy procedure. Directly after the bronchoscopy a chest-X-ray will be performed for safety evaluation to confirm no presence of pneumothorax or adverse event from the procedure.

Study burden and risks

Patients will be screened under regular medical care for surgery. Due to the bronchoscopy the anesthesia time will be 10 minutes extended. The bronchoscopy cares a small risk of pneumothorax. Participating patients have no personal gain or benefit.

Contacts

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Subject is scheduled within 60 days, for a total lobectomy or pneumonectomy procedure unrelated to this study (upper and lower lobes only).
Subject has a pre-procedure post bronchodilator FEV1 of greater than or equal to 50% of predicted.

Exclusion criteria

Subject is pregnant, nursing, or planning to get pregnant during study duration.
Subject has had prior radiation therapy which involved the lungs.
Subject has received chemotherapy within the past 6 months, or is anticipated to be treated with chemotherapy between initial study treatment and lobectomy/pneumonectomy procedure.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2014
Enrollment:	10

Type:	Actual

Ethics review

Approved WMO Date:	06-08-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT02106143
CCMO	NL48864.042.14