Assessment of the Safety and Performance of the AB1 Electrosurgical System for Bronchoscopic Microwave Ablation of Lung Tissue in Surgical Candidates (AB1MALTISC)

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The overall purpose of this study is to characterise the clinical safety and performance of the AB1 instrument in patients with pathologically confirmed malignancy eligible for surgical resection of their nodule, receiving bronchoscopic ablation…

Ethical review	Approved WMO
Status	Pending
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON56952

Source
ToetsingOnline

Brief title
AB1MALTISC

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified
- Respiratory tract neoplasms
- Respiratory tract therapeutic procedures

Synonym
lung cancer, lung carcinoma

Research involving

Human

Sponsors and support

Primary sponsor: Creo Medical Limited
Source(s) of monetary or material Support: The study is funded by Creo Medical Limited;the manufacturer of the investigational device (AB1 MicroBlate Flex instrument).

Intervention

Keyword: Ablation, Lung, Neoplasms, Resection

Outcome measures

Primary outcome

The primary safety objectives are as follows: Stage A - Ablate (Day 0) & Resect (Day 0) To assess and characterize any serious device-related intra-procedural adverse events associated with the delivery of microwave energy by the AB1 system in subjects undergoing bronchoscopic pulmonary nodule ablation prior to the first surgical incision for the resection. Stage B - Ablate (Day 0) & Resect (Resection Day 7-21) To assess and characterize any serious device-related adverse events associated with the delivery of microwave energy by the AB1 system in subjects undergoing bronchoscopic pulmonary nodule ablation (prior to the first surgical incision for the resection), in subjects who will undergo surgical resection. The primary performance (efficacy) objective is: To evaluate the ability of the AB1 instrument to bronchoscopically be positioned in the targeted lung tissue confirmed by fluoroscopy, CBCT or direct bronchoscopic vision and deliver scheduled microwave energy to the targeted tissue. The primary safety endpoint/outcome measures are as follows: Stage A - Ablate (Day 0) & Resect (Day 0) Identification of serious device-related intra-procedural adverse events

related to the use of the AB1 system on Day 0 prior to surgical resection defined by the initial skin incision (number and nature of serious adverse events, both device- and procedure related, will be identified). Stage B - Ablate (Day 0) & Resect (Resection Day 7-21) Identification of serious device-related adverse events related to the use of the AB1 system from day 0 up to initiation of surgical resection procedure (number and nature of serious adverse events, both device- and procedure related, will be identified). The primary performance endpoint/outcome is: Initial technical success, defined as successful bronchoscopic access by the AB1 instrument of the target tissue, delivery of scheduled microwave energy to the target tissue (per pre-specified target) and confirmed ablation as evidenced by macroscopic assessment post-surgical resection of the ablated lesion.

Secondary outcome

Secondary performance objectives:

To correlate the volumes and dimensions of thermally affected tissue provided in Creo Medical AB1 instrument instructions for use (obtained in ex vivo porcine lung tissue) with the dimensions and volumes measured in lung nodules using the AB1 System to deliver microwave energy for the same period, during the proposed clinical study.

To evaluate the ease of use of the AB1 System, including physician assessments of set-up, treatment selection, advancement and withdrawal of the AB1 Instrument from the bronchoscope, and electrosurgical system clean up, and instrument disposal.

Secondary performance endpoints/outcome measures:

1. Assessment/visualization/quantification of the dimensions of the ablated tissue including assessment of margin relative to lesion.*

2. Assessment/visualization/quantification of the dimensions of the ablation observed within the post-ablation CT.

3. Procedural Time

4. Assessment of ease of system use, including:

a. Clarity of instructions as reported by clinicians on a Likert scale of 1 to 7, with 1 being *extremely clear* and 7 being *extremely difficult to follow*.

b. Ease of set up as reported by clinicians on a Likert scale of 1 to 7, with 1 being *extremely easy* and 7 being *extremely difficult.*

c. Ease of selection of instrument from drop-down menu as reported by clinicians on a Likert scale of 1 to 7, with 1 being *extremely easy* and 7 being *extremely difficult.*

d. Ease of selecting treatment (power delivery time) using the diagrams and figures provided in the IFU, as reported by clinicians on a Likert scale of 1 to 7, with 1 being *extremely easy* and 7 being *extremely difficult.*

e. Ease of footswitch use to control energy delivery as reported by clinicians on a Likert scale of 1 to 7, with 1 being *extremely easy* and 7 being *extremely difficult.*

f. Ease of advancing AB1 instrument through bronchoscope to target tissue as reported by clinicians on a Likert scale of 1 to 7, with 1 being *extremely easy* and 7 being *extremely difficult.*

g. Ease of withdrawing AB1 instrument from bronchoscope as reported by clinicians on a Likert scale of 1 to 7, with 1 being *extremely easy* and 7 being *extremely difficult.*

h. Ability to visualize the AB1 antenna using CT as reported by clinicians on a Likert scale of 1 to 7, with 1 being *extremely easy* and 7 being *extremely difficult.*

i. Ease of ability to maintain a sterile field using the Sterile Sheaths as reported by clinicians on a Likert scale of 1 to 7, with 1 being *extremely easy* and 7 being *extremely difficult.*

j. Ease of disposal of contaminated instruments and accessory interface cable and sterile sheaths, as reported by clinicians on a Likert scale of 1 to 7, with 1 being *extremely easy* and 7 being *extremely difficult.*

Study description

Background summary

Lung cancer is the leading cause of cancer death in the world. Due to the lack of symptoms, it is not uncommon for lung cancer to present in late stages contributing to its high mortality. Lung cancer accounts for 20% of all cancers in men, with a lifetime risk of 1 in 13 men, and accounts for 12% of all cancers in women with a lifetime risk of 1 in 23 women. Worldwide, lung cancer incidence is estimated at 1.6 million, with approximately 1,095,200 cases in males and 513,600 in females. In 2008 there were 724,300 new diagnoses in the developed world and 884,500 new patients diagnosed with lung cancer in the developing world. The global burden of lung cancer has increased dramatically in recent years, reflecting the smoking epidemic that continues to affect the developing world. In addition to primary cancer being common, the lungs are also a frequent site for early metastases from renal, colon, and breast cancers.

The lung has 24 generations in the typical person. A standard bronchoscope can visualize and directly sample lesions within these proximal generations. Outside of this range, several tools, including ultra-thin bronchoscopes, radial probe endobronchial ultrasound (rEBUS), electromagnetic navigation (EMN), Cone Beam Computed Tomography (CBCT) assisted bronchoscopy can assist in the diagnosis of peripheral disease. After the diagnosis, bronchoscopic staging is completed using the endobronchial ultrasound guided transbronchial needle aspiration (EBUS-TBNA) bronchoscope. The diagnosis, its location, and the stage will dictate therapeutic options.

Surgery remains the gold standard treatment for patients with early-stage resectable disease who are operatively fit, while stereotactic body radiotherapy (SBRT) is the most common therapy offered for those patients that decline surgery or who have an unacceptable perioperative risk profile. Clinical equipoise between surgery and SBRT is purported, however, significant methodological challenges were met during each of the two primary studies investigating this relationship, with further randomized data needed. Patients undergoing interventional therapy for lung cancer are frequently co-morbid, with substantial post-operative morbidly recognized. SBRT delivers precise, very intense doses of radiation, with self-limiting fatigue very common, while pneumonitis, dyspnoea, chest pain, and pneumonia are recognized to occur in 2.7 - 27%. Furthermore, and, while rates of clinically significant lung toxicity following SABR are low, there is growing evidence that subpopulations of patients (i.e. with underlying lung fibrosis) are at increased risk. Finally, chest wall toxicity from SABR may include rib fractures or pain. Chest wall pain is reported in approximately 10% of patients, with grade 3 toxicity in about 2.0% and a median time to onset of >= 6 months following treatment.

Computer tomography (CT) guided microwave ablation, radiofrequency ablation and cryoablation are alternative treatments for small lung lesions but necessitates a needle being passed through the lung, to effect percutaneous ablation. An intrinsic risk of pneumothorax and haemorrhage is therefore associated with percutaneous access of lung lesions.

Targeted ablation with an endobronchial microwave instrument such as Creo Medical*s AB1 instrument offers the potential for focal treatment, whilst potentially avoiding the risks and morbidity associated with surgery, percutaneous ablation, or SBRT. When utilized in conjunction with an endobronchial navigation platform and/or cone beam CT, an ablation instrument can be reliably manoeuvred to target traditionally difficult-to-access lesions in the middle and peripheral thirds of the lung. This study investigates whether microwave energy can be safely delivered to the lung nodules, facilitating the effective ablation of a target lesion, while relatively preserving the surrounding parenchymal tissues and avoiding the risks associated with percutaneous access.

Study objective

The overall purpose of this study is to characterise the clinical safety and performance of the AB1 instrument in patients with pathologically confirmed malignancy eligible for surgical resection of their nodule, receiving bronchoscopic ablation prior to surgery.

Study design

Post-market, prospective, single-arm, multicentre, open-label, non-randomized study.*The study consists of two (2) sequential stages (Stage A and Stage B).*Stage A consists of the ablation and the surgical resection being performed concurrently on Day 0 within a single procedure.*Stage B consists of the ablation and the surgical resection being performed in separate procedures.*In Stage B the surgical resection will occur between Day 7 and Day 21, post-ablation, inclusive of those days. The aim is to follow local guidelines for treatment of lung cancer. Transition from Stage A to Stage B may begin when the below criteria are met:

• 15 patients enrolled and treated within either Stage A of this study (CIP ID: PD-GTD-AB1-003) and/or from the AB1MALT study (CIP ID: 8-AB1-950). NOTE - a minimum of 3 patients must be treated in Stage A of this study. .
• It should be noted that no investigative site will transition from Stage A to Stage B if any of the following have occurred:
• In case of 1 death that can be related to the ablation procedure/device, OR
• In case of 1 of the following events:
• Severe complication related to the ablation/device occurs that lead to cancellation of the resection directly after ablation.

• Severe haemorrhage (definition of severe haemorrhage = bleeding lasting longer than 30 minutes after all potential interventions that could solve the bleeding have been employed (Cold NaCL, vasoconstrictors, intravenous drugs, bronchus blockers) or surgical intervention is needed to treat the bleeding.
• The occurrence of the above ablation/device related events will trigger a full review (meeting) of the DMC, at which time the DMC may make a recommendation to terminate, suspend, or amend the trial or trial protocol, as appropriate.

- Note: transition from Stage A to Stage B is not mandatory and patients may continue to be enrolled in the study up to the maximum enrolment target for concurrent Ablate and resect (Day 0) procedures.
- Note: At any point within the study (even if one (1) or more patients have been enrolled for Stage B), patients may still be enrolled for concurrent Ablate and Resect (Day 0) procedure (Stage A) if they elect not to enrol for a Stage B procedure.

Patients undergoing Stage A will be released from the study at point of standard of care discharge from hospital post-surgery and will not be followed as part of the study (patients will receive SoC follow-up and care post release from study).

Patients undergoing Stage B will have evaluations at follow-up visits conducted at 7 to 10 days (via phone call) post ablation and prior to the surgical resection procedure. Stage B patients will be released from the study at point of standard of care discharge from hospital post-surgery and will not be followed as part of the study (patients will receive SoC follow-up and care post release from study).

Intervention

The subject device, the AB1 electrosurgical system is CE Marked for soft tissue ablation. The device has not been modified and is being used in accordance with its intended purpose.

The MicroBlate Flex (AB1) System delivers focused microwaves to soft tissue and can be used to treat cancerous and non-cancerous lung nodules. The AB1 instrument is advanced through a long flexible camera called a bronchoscope, that has first been passed via the mouth and into the lungs, whilst the subject is under general anaesthetic.

Participation in this study will include a screening visit, a pre-procedural assessment, a bronchoscopy procedure that includes MicroBlate Flex treatment, followed by surgical removal of the treated lesion. A post-procedural assessment will be made, and follow-up care will be in accordance with the

routine practice of the participant's Doctor and Hospital.

Study burden and risks

Potential risks of study participation are:
· Delay to surgical procedure
· Radiation exposure from study-related CTs
· Injury to bronchi causing bleeding or perforation
· Pulmonary Infections
· Damage to non-target lung tissue
· Risks associated with bronchoscopy (common side effects: wheezing, cough, sore throat, hoarseness, tension in the throat)
· Risks associated with general anaesthesia

Potential serious adverse events, adverse events, or adverse devices effects include the following:
• Pneumothorax
• Hemothorax
• Infection/toxicity/pyrogenicity
• Pneumomediastinum (air in the chest between the lungs)
• Fistula
• Air embolism
• Arrhythmia/Ventricular fibrillation
• Bleeding requiring treatment or resulting in prolonged hospitalization
• Hypoxia
• Pleural effusion (water around the lungs)

The participant may receive no personal benefit from the proposed AB1 ablation treatment.

Potential benefits of study participation include:
• Contribution to the base of knowledge addressing microwave ablation of lung tissue, which could result in improvements to instruments and procedures used to treat lung cancer in the future, resulting in improved healthcare and quality of life for people with lung cancer.
• The ability to reach the periphery of the lung endoluminally may also provide a reduced complication rate relative to percutaneous ablation approaches.

This study is being conducted to assess the safety and performance/efficacy of the intervention and to extend our knowledge about use of the Creo MicroBlate electrosurgical system and the bronchoscopic approach to assessing and ablating lung lesions. Endobronchial ablation may prevent or minimize the need for invasive surgery to treat lung lesions and lead to shorter patient recovery times, a reduced incidence of complications, decreased hospital stays, and improved quality of life for lung cancer patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients who: 1. Have signed informed consent. 2. Subject is willing and able to comply with all aspects of the treatment and evaluation schedule. 3. Are >= 18 years old. 4. Have lung lesion(s)/nodule(s) which are histopathologically confirmed as cancer. 5. Have soft tissue lung lesion(s): • <= 30 mm in the largest dimension of the pulmonary window for Stage A • <= 20 mm in the largest dimension of the pulmonary window for Stage B 6. Are candidates for surgical resection as determined by a multi-disciplinary team (MDT) or tumour board. 7. > 10 mm of tumour-free lung parenchyma between target tumour and pleura or fissure. 8. Subject is willing and able to comply with the study protocol requirements. 9. Are assigned an ASA (American Society of Anaesthesiologists) score of <= 3 or the patient is deemed fit for general anaesthesia.

Exclusion criteria

Patients who: 1. Have target nodule(s) within the International Association for the Study of Lung Cancer (IASLC) *Central Zone* (including bronchial tree, major vessels, heart, oesophagus, spinal cord, and phrenic & laryngeal nerves). 2. Are pregnant or breast feeding, as determined by standard site practices. 3. Have participated in an investigational drug or device research study within 30 days of enrolment that would interfere with this study. 4. Have a physical or psychological condition that would impair study participation or jeopardise the safety or welfare of the subject. 5. Have an expected survival less than 12 months. 6. Have bleeding diathesis, uncorrectable coagulopathy, or platelet count <= 100 x 10* /L. 7. Have an implantable device, including pacemakers or other electronic implants. 8. Have known pulmonary hypertension (PASP [pulmonary artery systolic pressure] >50mmHg). 9. Who are currently prescribed anticoagulants, clopidogrel or other platelet aggregation inhibitors which can*t be stopped or temporarily withheld. 10. Subject had a prior pneumonectomy. 11. Diagnosis of Small Cell Lung Cancer. 12. Any patient with clinically significant interstitial lung disease in the zone of planned ablation. 13. Subject had a therapeutic intervention (e.g., SBRT) within same lobe as the target lesion. 14. Subjects currently undergoing or underwent chemotherapy, systemic immunosuppressive treatment, or radiotherapy within 3 months of planned Study procedure.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	20-05-2024
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	AB1 (MicroBlate Flex) instrument
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	02-08-2024
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NCTnumber-tobeassigned
CCMO	NL83638.018.23