Assessment of the Safety and Performance of the AB1 Electrosurgical System for Bronchoscopic Microwave Ablation of Lung Tissue (AB1MALT)

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The overall purpose of this study is to confirm the clinical safety and performance of the AB1 instrument in subjects undergoing bronchoscopic pulmonary nodule microwave ablation procedures performed using the AB1 electrosurgical system.

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

Summary

ID

NL-OMON56949

Source
ToetsingOnline

Brief title
AB1MALT

Condition

- Soft tissue 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, Bronchoscopy, Lung, Neoplasms

Outcome measures

Primary outcome

Primary Safety Objective:

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 compared to the adverse events identified in the peer-reviewed literature (CER) or risk assessment for the ablation of lung soft tissue, in subjects who are not candidates for, or decline, surgical resection.

Primary Safety Endpoint:

Identification of serious device-related adverse events related to the use of the AB1 system from up to 30 days after the ablation procedure (number and nature of serious adverse events, both device- and procedure-related, will be identified) including but not limited to:

• Moderate bleeding (intervention required such as use of balloon tamponade or Surgicel) or severe bleeding (prolonged monitoring necessary or fatal bleeding)

• Pneumothorax

• Failure of extubation

• ICU admission for respiratory failure within 30 days

• Death within 30 days.

Primary Performance Objective:

To evaluate the ability of the AB1 instrument to bronchoscopically be positioned in the targeted lung tissue and deliver scheduled microwave energy to the targeted tissue.

Primary Performance Endpoint:

Initial technical success, defined as successful bronchoscopic access by the AB1 instrument of the target tissue, delivery of the scheduled microwave energy to the target tissue (per pre-specified target) and confirmed ablation as evidenced by assessment of CT on day 0 (post ablation) or up to day 30 patient visit.

The criterion for meeting the Performance (efficacy) endpoint excludes study system malfunctions.

Secondary outcome

Secondary Safety Objective:

To assess the clinical safety of AB1 system ablation of pulmonary nodules.

Secondary Safety Endpoint:

Identification of all device-related, procedure related and other adverse

events related to bronchoscopic microwave ablation interventions using the AB1 system with follow-up at 1, 7 and 31 to 45 days, and at 3, 6, 9, and 12 months, post-ablation.

Secondary Performance (Efficacy) Objectives:

To assess the clinical efficacy of AB1 system ablation of pulmonary nodules.

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 human lung tissue using the AB1 System to deliver microwave energy for the same period, during the proposed clinical study.

To evaluate the impact of using the AB1 system on patient quality of life, in subjects undergoing pulmonary nodule ablation.

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 Outcome Measures:

1. Rate of recurrence at all time points as determined by the multidisciplinary team (MDT) or tumour board.

2. European Organization for Research and Treatment of Cancer Quality of life questionnaire - Cancer (EORTC) QLQ- C. Patients will rate their responses from 1 to 4 on a Likert Scale (1 being *not at all* and 4 being *very much*). [Time Frame: Within 2 months prior to the ablation, on the day of the ablation (prior to ablation), on the day after ablation, and 31 to 45 days, 6 months and 12 months post-ablation].

3. EQ-5D-5L health-related quality of life questionnaire. Patients complete the 5 level descriptive system relating to 5 dimensions of health and the EQ visual analogue scale. [Time Frame: Within 2 months prior to the ablation, on the day of the ablation (prior to ablation), on the day after ablation, and 31 to 45 days, 6 months and 12 months post-ablation].

4. Patient-reported pain rating on a visual analogue scale from 0 to 10 (where 0 is no pain and 10 is the most severe pain) [Time Frame: Within 2 months prior to the ablation, on the day of the ablation (prior to ablation), on the day after ablation, and at 31 to 45 days post-ablation].

5. Assessment/visualization/quantification of the dimensions of the ablated tissue to confirm, correct or add to the IFU-reported relationship between AB1 ablation time and dimensions and volume of the ablated tissue, per pre-specified target.

6. Procedural Time.

7. Assessment of ease of system use (clinician questionnaires). Questionnaires to be completed by clinicians, rating their responses 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 one of the most common malignancies (cancers) and it has the second highest death rate of any neoplasm (tumour) globally.

This study is designed to assess whether microwave ablation (heating to destructive temperature) using the Creo Medical MicroBlate Flex (AB1) System can be used to avoid the need for participants who have lung nodules to undergo surgery. This study is not randomised and there is no control or placebo group, meaning that it is planned that all participants in the study will undergo microwave ablation.

The study will answer questions related to safety and performance with objectives including assessment of technical success (delivery of microwave energy to ablate lung tissue) and assessment of device related adverse events (meaning any harm to the participant).

Potential benefits to the participant include, effective bronchoscopic (procedure performed with a small flexible tube with camera to examine the airways) microwave ablation of the lung lesion (without the need for surgery), reduced duration of hospital stay and improved quality of life.

Potential future benefits for other people who have the same medical conditions include the choice to select bronchoscopic microwave ablation treatments of lung tissue lesions and the avoidance of surgery for future patients who are surgical candidates and improved quality of life.

The MicroBlate Flex (AB1) System has been approved for use in Europe. The study, funded by Creo Medical, will be conducted in UK, Europe and possibly the US, and will involve up to 32 participants. This is a post-market prospective, single-arm, multicenter, open-label, non-randomized study.

The participation in this study will last up to a maximum of approximately 12 months. The participation will include a screening visit, a pre-procedural assessment, a bronchoscopy procedure that includes MicroBlate Flex treatment, a post-procedural assessment and 6 follow-up visits at, 7 days (by phone call or in person), 31-45 days, 3 months, 6 months, 9 months and 12 months.

Study objective

The overall purpose of this study is to confirm the clinical safety and performance of the AB1 instrument in subjects undergoing bronchoscopic pulmonary nodule microwave ablation procedures performed using the AB1

electrosurgical system.

Study design

This is a post-market, prospective, single-arm, multicentre, non-randomized, observational study which will enrol up to 32 subjects in total (plus replacements) at up to 6 clinical investigation sites in Europe and possibly up to 1 site in the US. The study is designed to assess the safety and performance of bronchoscopic microwave ablation of lung tissue using the Creo Medical AB1 (MicroBlate Flex) System.

Intervention

All patients enrolled in the study will undergo the AB1 MicroBlate Flex bronchoscopic microwave ablation procedure.

Study burden and risks

Potential risks of study participation are:
• Incomplete treatment
• Radiation exposure from study-related CTs
• Injury to the lung 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 that requires treatment or leads to prolonged hospitalization
• Hypoxia
• Pleural effusion (water around the lungs)

The bronchoscopy procedure will be performed under general anaesthesia to minimise patient discomfort.

No additional risks beyond standard clinical care and standard administration

of anaesthesia are anticipated.

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

Potential benefits of study participation include:
• Effective bronchoscopic microwave ablation of the lung lesion, without the need for surgery;
• Reduced duration of hospital stay
• Improved quality of life.

Participation has the potential to provide the following benefits for other people who have the same medical conditions:
• Choice to select bronchoscopic microwave ablation treatments of lung tissue lesions and the avoidance of surgery for future patients who are surgical candidates
• Improved quality of life.

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. Are >= 18 years old.
3. Have lung lesion(s)/nodule(s) which are histopathologically confirmed or are highly suspicious for cancer and is a candidate for bronchoscopic microwave ablation (as determined by a multi-disciplinary team (MDT) or tumour board).
4. Have medically inoperable soft tissue lung lesion(s) <= 20 mm (suspected or confirmed malignancy), or a patient has elected not to have surgery / alternative therapy.
5. Patient is a candidate for bronchoscopy under general anaesthesia.
6. Subject is willing and able to comply with the study protocol requirements.
7. 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. Target nodule(s) are 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) or are <10 mm from the pleura. 2. Are assigned status 4 via ECOG (Eastern Cooperative Oncology Group) classification. 3. Are pregnant or breast feeding, as determined by standard site practices. 4. Have participated in an investigational drug or device research study within 30 days of enrolment that would interfere with this study. 5. Are scheduled for concurrent interventional procedure for the target soft tissue lesion. 6. Have a physical or psychological condition or other factor(s) that would impair study participation or jeopardise the safety or welfare of the subject. 7. Have an expected survival less than 6 months. 8. Have bleeding diathesis, uncorrectable coagulopathy or platelet count <= 100 x 10* /L. 9. Have an implantable device, including pacemakers or other electronic implants. 10. Have known pulmonary hypertension (PASP [pulmonary artery systolic pressure] >50mmHg). 11. Who are currently prescribed anticoagulants, clopidogrel or other platelet aggregation inhibitors which can*t be stopped or temporarily withheld. 12. Any patient with clinically significant interstitial lung disease in the zone of planned ablation. 13. Patient has nodal disease confirmed through invasive or image-based staging. Note: if nodal disease is suspected or detected during the staging procedure conducted prior to use of the investigational device during the study procedure, the subject will be excluded. 14. Subject had a prior

pneumonectomy.

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	NCT05786625
CCMO	NL83863.018.23