

Safety and Efficacy of Cryoablation With Karelizumab and Apatinib for Multiple Lung Cancers

NCT06607770

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Zhou Chengzhi
Enrollment	20 participants

Plain Language Summary

This study tests whether combining cryoablation (a procedure that freezes and destroys tumors) with an immunotherapy drug (camrelizumab) and a targeted therapy (apatinib) can help treat people with multiple lung cancers — specifically those who have more than 2 small lung nodules remaining after previous surgery.

****You may be eligible if...****

- You are between 18 and 75 years old
- You have been diagnosed with multiple primary lung cancers
- You have at least 3 lung nodules at diagnosis or before surgery, with no spread to lymph nodes
- The largest nodule is 3 cm or smaller
- After previous lung surgery, at least 2 nodules remain, confirmed as minimally invasive or in-situ lesions
- You are in good general health (ECOG performance score 0–1)
- Your expected survival is at least 12 weeks

****You may NOT be eligible if...****

- Your nodules are larger than 3 cm
- You have lymph node involvement
- You do not meet minimum blood count and organ function requirements

Talk to your doctor to see if this trial is right for you.

Key Eligibility Criteria

Inclusion (11)

- Clinical and pathological diagnosis of multiple primary lung cancers
 - There were 3 intrapulmonary nodules at the initial diagnosis or preoperative, and there was no lymph node metastasis
 - The maximum lesion diameter is ≤ 3 cm
 - At most, patients have undergone surgical resection treatment, and there are ≤ 2 remaining intrapulmonary nodules, and the postoperative pathology confirms that it is MIA or AIS
 - It is estimated that at least 1 measurable lesion meeting RECIST v1.1 criteria will remain after cryotherapy
- ... and 6 more (see full listing online)

Exclusion (10)

- Patients with known EGFR mutations, ALK rearrangements;
- Conditions that cannot be treated with cryoablation: diffuse lesions in both lungs, extensive pleural metastases with large pleural effusions, tumors adjacent to or encircling large mediastinal vessels, etc;
- Prior receipt of anti-PD-1, anti-PD-L1, anti-CTLA-4 antibodies, or any other antibody or drug targeting T cell co-stimulation or immune checkpoint pathways;

• Received the following treatments: a. Received systemic anti-tumor therapy such as chemotherapy, targeted therapy, immunotherapy, etc. within 4 weeks prior to randomization; b. Treatment with any investigational drug within 4 weeks prior to

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randomization;c.Receipt of high-dose immunosuppressive medications (systemic glucocorticoids greater than 10 mg/day of prednisone or its equivalent) within 4 weeks prior to randomization;d.Major surgery (such as open, thoracotomy, or laparotomy, etc.), or unhealed surgical wounds, ulcers, or fractures within 4 weeks prior to randomization.

- Known or suspected active autoimmune disease (congenital or acquired);

... and 5 more (see full listing online)

Locations (1 total)

Chengzhi Zhou, Guangzhou, Guangdong, China