A phase II study of stereotactic body radiation therapy in patients with T1N0M0 non-small cell lung cancer (JCOG-0403)

Study chair

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Purpose

- To evaluate the safety and efficacy of stereotactic body radiation therapy (SBRT) for T1N0M0 NSCLC

  ? SBRT as a standard care in medically inoperable patients

  ? SBRT as a treatment option in operable patients

Eligibility criteria

- Pathologically proven NSCLC.
- Stage IA
- Medically inoperable or operable (who prefer non-surgical treatment)
- PS 0-2
- $PaO_2 \geq 60$ torr
- $FEV_{1.0} \geq 700$ ml
- Written informed consent

Stereotactic irradiation

- 48 Gy/4 fx over 4-8 days
- Prescription point is the isocenter
- Dose constraints for organs at risk are defined
- Lung heterogeneity correction will be used in MU calculation
- D_{95}, Homogeneity Index (HI), and Conformity Index (CI) will be recorded

Endpoint and sample size

- Primary endpoint: 3-year overall survival
- Sample size：165

  -Operable, 65; Inoperable, 100

  -Accrual: 3 years

Participating institutions

- Hokkaido University
- Tohoku University
- Cancer Institute Hospital
- Metropolitan Komagome Hospital
- Keio University
- Hiroshima University
- Kitazato University
- Yamanashi University
- Sapporo Medical College
- Tokyo University
- Nippon University
- Tokyo Women's Medical University
- Tenri Yorozu Hospital
- Institute of Biomedical Research and Innovation
- Kyushu University
- Kyoto University