# A Crossover Study to Compare Lung Flute Method to Hypertonic Saline Inhalation for the Examination of *M. tuberculosis* in Induced Sputum (UMIN 000004676)

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## Introduction

- Lung flute (LF) is a handy audio device for promoting sputum expectoration.
- Fujita showed usefulness of LF for the rapid diagnosis of pulmonary TB.
- WHO introduced LF as an innovative diagnostic device for pulmonary TB.
- However, there's no study to compare LF with conventional sputum induction.

## Aims

To clarify whether LF is equivalent to hypertonic saline inhalation (HSI) as a sputum induction method for the diagnosis of pulmonary TB

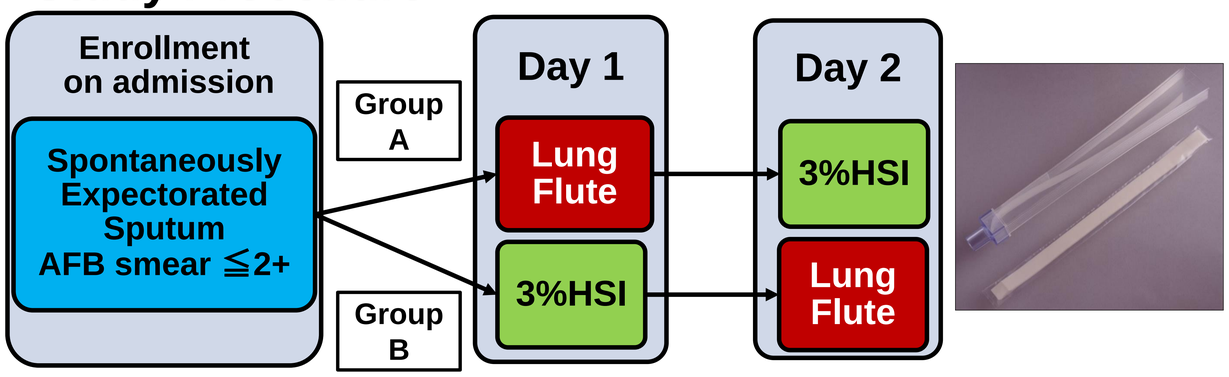
## Methods

**Study period:** Dec. 2010-Nov. 2013, Study site: 6 hospitals in Japan
**Study design:** Multi-center non-blinded crossover study

**Inclusion:** Age≧18 years, Hospitalized pulmonary TB
Spontaneously expectorated sputum AFB smear≦2+

**Exclusion:** Sputum AFB smear 3+, Possible to expectorate sputum anytime, Asthma, Hemoptysis, Hypoxemia (SpO2 <90%)

### Study Procedure






**Lung flute Method**

1. Hold mouthpiece after deep inhalation. 2. Blow into Lung Flute twice.
3. Rest for > 2 normal breaths. 4. Repeat above process for 20 times.

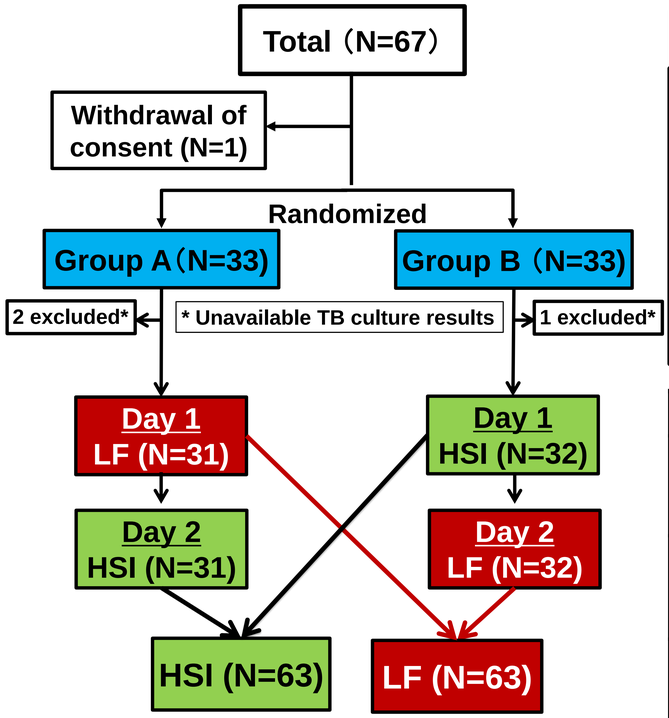
**Diagnostic Performance (Major Endpoint)**

- ◆Sputum AFB smear score distribution
- ◆Liquid culture positivity yield, Time to positive (MGIT)
- ◆MTB-PCR positivity yield

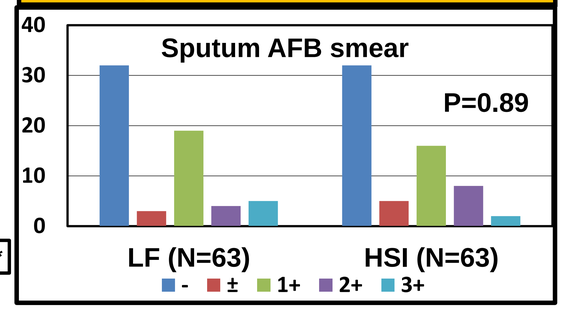
**Adverse Events (Secondary Endpoint)**

**Statistical analysis** Fisher's exact test for comparing ratios, Student's t-test or Wilcoxon rank-sum test for comparing continuous variables, Difference regarded as statistically significant when p value <0.05. STATA version 12.1 was use as the statistic software.

## Results




### Diagnostic Performance




| | LF | HSI | p value |
|---|---|---|---|
| Culture (+) N (%) | N=63<br>52 (82) | N=63<br>54 (85) | 0.72 |
| Time to (+) [IQR], day | N=46<br>13 [9-16] | N=46<br>12 [8-16] | 0.51 |
| TB-PCR(+) N (%) | N=51<br>43 (84) | N=51<br>40 (78) | 0.50 |

### Basic Characteristics

| | Group A (N=31) | Group B (N=32) | P value | Total (N=63) |
|---|---|---|---|---|
| Age±SD | 62±17 | 56±17 | 0.19 | 59±17 |
| Sex Male, n (%) | 20 (64.5) | 23 (68.7) | 0.79 | 44 (66.6) |
| BMI±SD (kg/m²) | 20±3 | 20±2 | 0.72 | 20±3 |
| Chest X-ray | | | | |
| Cavity (+) | 13 (43) | 15 (46) | 0.80 | 28 (45) |
| Extensive lesion | 3 (10) | 4 (12.5) | N.S. | 7 (11) |

### Adverse Events

| N (%) | LF | HSI | p value |
|---|---|---|---|
| ≧3% Desaturation | 2 (3.1) | 7 (11.1) | 0.08 |
| Throat discomfort | 0 (0.0) | 2 (3.1) | 0.24 |
| Throat pain | 1 (1.5) | 6 (9.2) | 0.11 |
| Dyspnea | 2 (3.1) | 2 (3.1) | N.S |
| Wheezing | 2 (3.1) | 2 (3.1) | N.S. |
| Severe cough | 3 (4.6) | 2 (3.1) | N.S. |
| Numbness | 0 (0.0) | 1 (4.6) | N.S. |

## Conclusion

- LF was equivalent to HSI as a sputum induction method regarding the bacterial diagnostic performance of pulmonary TB.
- LF tended to have less throat related adverse events compared with HSI.
- LF is feasible sputum induction device for diagnosis of pulmonary TB.

**References:**
Fujita A, Murata K, Takamori M. Respirology 2009;14:899–902.
World Health Organization. Compendium of innovative health technologies for low-resource settings: Assistive devices. eHealth solutions. 2013;1–124.

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