

# Comparison of three diagnostic tools for latent tuberculosis in haemodialysis patients

<b>Submission date</b> 18/03/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 26/03/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 26/03/2008	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

## Study information

**Scientific Title**

### Study objectives

Latent tuberculosis is hard to diagnose in immunocompromised hosts like haemodialysis patients, and widespread bacille calmette-guerin (BCG) vaccination make it complicated to

interpretate Mantoux test results in Korea. Therefore, we need more sensitive and specific diagnostic tools for latent tuberculosis in haemodialysis patients.

Hypothesis:

T-spot assay or Quantiferon assay is more sensitive and specific than Mantoux test for latent tuberculosis in haemodialysis patients.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Ethics approval received from the Institutional Review Board (IRB) of Gachon University of Medicine and Science on the 28th February 2008 (ref: 20080228 tuberculosis in haemodialysis).

### **Primary study design**

Observational

### **Study design**

Single centre, observational, cross-sectional, open trial

### **Study type(s)**

Diagnostic

### **Health condition(s) or problem(s) studied**

Latent tuberculosis

### **Interventions**

Agreement of three diagnostic tests for latent tuberculosis will be tested in haemodialysis patients. Blood samples are taken for:

1. Quantiferon-gold assay, an enzyme linked immunosorbent assay (ELISA) assay for interferon gamma in response to tuberculosis specific antigens
2. T-spot assay, an enzyme-linked immunosorbent spot (ELISPOT) assay for interferon gamma

After sampling, the Mantoux test will be performed, and the results will be read in two days. Agreement of three test results will be analysed using kappa coefficients, and results will be analysed per each categories of risk groups such as low risk group, casual contact group, latent tuberculosis patients, and active tuberculosis patients. Agreement will be also analysed in medical staff group with normal immunity.

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome(s)**

1. Skin test: positive or negative
2. Quantiferon-gold: positive or negative
3. T-spot test: positive or negative

These outcomes will be measured on the day of testing.

**Key secondary outcome(s)**

1. Skin test: size of induration
2. Quantiferon-gold: concentration
3. T-spot test: number, mean area

These outcomes will be measured on the day of testing.

**Completion date**

30/04/2008

**Eligibility****Key inclusion criteria**

1. Chronic maintenance haemodialysis patients who continue to receive haemodialysis for more than three months in the Gil Medical Centre
2. Older than 18 years, and less than 80 years, either sex
3. Agrees to participate in this trial
4. Medical staff in the haemodialysis centre of the Gil Medical Centre

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

80 Years

**Sex**

All

**Key exclusion criteria**

1. Patients who suffer from skin diseases which may interfere with Mantoux test
2. Patients with an active infection, except tuberculosis
3. Patients who cannot make independent decision due to mental disorders

**Date of first enrolment**

01/03/2008

**Date of final enrolment**

30/04/2008

**Locations**

**Countries of recruitment**

Korea, South

**Study participating centre****Division of Nephrology**

Incheon

Korea, South

405-760

## Sponsor information

**Organisation**

Gachon University of Medicine and Science (South Korea)

**ROR**

<https://ror.org/03ryywt80>

## Funder(s)

**Funder type**

University/education

**Funder Name**

Gachon University of Medicine and Science (South Korea) - Division of Nephrology, Department of Internal Medicine

## Results and Publications

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration