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Comparison of three diagnostic tools for latent tuberculosis in haemodialysis patients

Submission date	Recruitment status	[_] Prospectively registered
18/03/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/03/2008	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
26/03/2008	Infections and Infestations	[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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).

Study design
Single centre, observational, cross-sectional, open trial

Primary study design
Observational

Secondary study design
Cross-section survey

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please contact Jaeseok Yang at jcyjs@hanafos.com to request a patient information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/03/2008

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
162

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)

Sponsor details
Institutional Review Board (IRB)
Department of Pharmacy
Gil Medical Centre
1198 Guwol-dong
Namdong-gu
Incheon
Korea, South
405-760

Sponsor type
University/education

Website
http://home.gachon.ac.kr/icc/

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration