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A randomised, placebo-control phase III study to assess the safety and efficacy of the MPT64 patch test in the diagnosis of active tuberculosis (TB)

Submission date
13/09/2005

Recruitment status
No longer recruiting

Registration date
11/11/2005

Overall study status
Completed

Last Edited
12/01/2021

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
SEQPTAT005

Study information

Scientific Title
A randomised, placebo-control phase III study to assess the safety and efficacy of the MPT64 patch test in the diagnosis of active tuberculosis (TB)

Study objectives
Cutaneous reaction to transdermal delivery of the Mycobacterium tuberculosis (MTB) specific protein MPT64 by means of a patch test will accurately identify individuals with active TB from amongst TB suspects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Active pulmonary tuberculosis.

Interventions
1. Diagnostic phase: application of a transdermal patch to each forearm, one containing placebo and the other MPT64 (study staff and patients blinded to allocation) with removal and reading of result at days 4 and 6. All patients receive full work-up for active pulmonary TB including clinical evaluation, two sputum cultures (each by two methods), chest radiograph and (on day 4) purified protein derivative (PPD) skin testing.
2. Follow-up phase: all participants are followed up at 3 months to verify correct baseline assignment as TB or non-TB; at months 9, 12, 15 and 18 all participants are investigated fully once more for TB (as above) and repeat patch testing is performed. In a subgroup of 30 consenting participants with positive reactions, skin punch biopsies are performed.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
MTB specific protein MPT64

Primary outcome(s)

The objective is to assess the sensitivity and specificity of the MPT64 patch test in the diagnosis of pulmonary TB - the outcome of interest is therefore the concordance of patch test results with the results of the conventional gold-standard investigations performed concurrently.

Key secondary outcome(s)
1. To assess the above performance characteristics in patient subgroups including those with smear-positive disease and smear-negative disease
2. To determine the effect (if any) of age, HIV status, PPD response upon patch test performance
3. To determine the response over time of both initial reactors and non-reactors and TB and non-TB patients
4. To characterize the histological response in patch test reactors

Completion date
01/05/2007

Eligibility

Key inclusion criteria
TB suspects undergoing investigation at selected health centres for pulmonary TB within the National TB Control Programme of Peru.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
512

Key exclusion criteria
1. Age less than 18 or greater than 65
2. Inability or unwillingness to provide written informed consent
3. Participation in a clinical trial of another investigational product within the preceding 6 months
4. Refusal to undergo voluntary counselling and testing for human immunodeficiency virus (HIV) infection

Date of first enrolment
20/02/2005

Date of final enrolment
01/05/2007

Locations

Countries of recruitment
Peru

Study participating centre
Universidad Peruana Cayetano Heredia
Lima
Peru
Lima 31

Sponsor information

Organisation
Sequella Inc (USA)

ROR
https://ror.org/0287vk548

Funder(s)

Funder type
Industry

Funder Name
Entirely funded by Sequella Inc.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2018	12/01/2021	Yes	No