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Mycobacteria infection in incomplete transverse myelitis

Submission date	Recruitment status	[ ] Prospectively registered
27/03/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
09/04/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
09/04/2010	Nervous System Diseases	[ ] 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

Protocol serial number
N/A

Study information

Scientific Title
Antituberculosis treatment in incomplete transverse myelitis in steroid-refractory patients: a prospective open label study

Acronym

ATT in myelitis

Study objectives
Incomplete transverse myelitis (ITM) of unknown origin is associated with high rates of morbidity and mortality, and treatment options for these patients are few. This pilot study was undertaken to determine whether antituberculous treatment (ATT) might help in patients with ITM whose condition continued to worsen despite receiving steroid treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the First Affiliated Hospital of Sun Yat-Sen University approved in June 2003

Study design
Prospective open-label pilot study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Incomplete transverse myelitis (ITM)

Interventions
Prior to ATT initiation, all treatments with corticosteroids and other systemic immunosuppression therapy were discontinued. Our treatment protocols consisted of three antituberculous drugs regimen (isoniazid, rifampicin and pyrazinamide were used for 9 months), followed by a combination of isoniazid and rifampicin until 24 months. The dose of isoniazid was 8 mg/kg/day, rifampicin was 10 mg/kg/day, and pyrazinamide 25 mg/kg/day. Treatment was under our extensive observation. All patients had the following weekly liver function tests for the first one month of therapy and subsequently every 3 monthly: serum bilirubin, serum transaminases (aspartate aminotransferase [AST]/alanine aminotransferase [ALT]) and alkaline phosphatase. All patients were followed up for at least 1 year after treatment.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Isoniazid, rifampicin, pyrazinamide

Primary outcome(s)
Before the start of the assigned treatment all patients had a baseline visit, at which the medical history was obtained, and physical and neurological examinations were undertaken. The American Spinal Injury Association (ASIA) standards were adopted to assess subjects' neurological status. We used the ASIA Impairment Scale to evaluate sensory and motor function

and neurological level. Activities of daily living (ADL) were assessed by Barthel Index (BI) (0 - 100 scale, with lower scores denoting less independence in activities of daily living); mobility were scored by the Hauser Ambulation Index.

Key secondary outcome(s))
1. Changes in quality of life, measured by the ASIA, BI and AI at baseline and at 12 months
2. MRI changes assessed at baseline and at 12 months

Each patient was followed up and assessed by the same physician during the study.

Completion date
01/06/2009

Eligibility

Key inclusion criteria
1. Development of sensory, motor, or autonomic dysfunction attributable to the spinal cord
2. Varying degrees of motor, sensory and sphincter dysfunction (though not necessarily symmetrical), but without complete paraplegia
3. Exclusion of extra-axial compressive aetiology by magnetic resonance imaging (MRI)
4. Worsened condition despite at least one 5-day course of intravenous (IV) methylprednisolone (0.5 - 1 g/d)
5. Cerebrospinal fluid mycobacterium tuberculosis (CSF MTB) culture were negative, with cell count less than 50/mm^3 and total protein less than 1.5 g/L
6. Aged 18 - 70 years, either sex

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Sudden onset
2. History of previous radiation to the spine within the last 10 years
3. Central nervous system (CNS) manifestations of syphilis, Lyme disease, human immunodeficiency virus (HIV) infection
4. Clear arterial distribution clinical deficit consistent with thrombosis of the anterior spinal artery
5. History of clinically apparent optic neuritis
6. Brain MRI abnormalities suggestive of multiple sclerosis (MS) and clinically definite MS

7. Serologic or clinical evidence of connective tissue disease (sarcoidosis, Behcet's disease, Sjögren's syndrome, systematic lupus erythematosis [SLE], mixed connective tissue disorder, etc)

Date of first enrolment
01/01/2003

Date of final enrolment
01/06/2009

Locations

Countries of recruitment
China

Study participating centre
Department of Neurology
Guangzhou
China
510080

Sponsor information

Organisation
Sun Yat-sen University (China)

ROR
https://ror.org/0064kty71

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (China)

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes