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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/01/2003

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
67 participants

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
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Sponsor information

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University/education

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Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (China)

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