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The auxiliary diagnostic value of fissured tongue in Ankylosing Spondylitis

Submission date
13/04/2017

Recruitment status
No longer recruiting

Registration date
03/05/2017

Overall study status
Completed

Last Edited
10/08/2017

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Ankylosing spondylitis (AS) is a long-term disease that causes inflammation (swelling) in the spine and other areas of the body. Symptoms include back pain, stiffness, swelling and tiredness. There is usually a delay in diagnosing AS as the symptoms are usually thought to be caused by general back pain. Fissured tongues (FT) are a condition where the surface of the tongue has deep grooves. In Traditional Chinese Medicine (TCM), fissured tongues are shown to have an impact on the auxiliary (additional) diagnostic value in AS. Other studies have shown that FT is more common in people with disease than in healthy individuals, for example people with psoriasis have an increased rate of FT. Other immune diseases have similar symptoms. The aim of this study is to identify whether fissured tongue (FT) has an auxiliary diagnostic value in ankylosing spondylitis (AS).

Who can participate?
Adults aged 15 to 67 years old who are diagnosed with ankylosing spondylitis.

What does the study involve?
Participants are allocated to one of two groups based on if they have a fissured tongue or not. All participants undergo three study visits spaced 12 weeks apart. They are assessed for their level of fissured tongue and their pain levels. Also, blood samples are taken to test specific markers and levels found in the blood. They also have scans taken of their spine. The results for each group are compared to see if fissured tongues have a diagnostic value in AS.

What are the possible benefits and risks of participating?
There are no notable benefits or risks with participating.

Where is the study run from?
This study is being run by the Zhejiang University of Chinese Medicine (China) and takes place in two affiliated hospitals (China).

When is the study starting and how long is it expected to run for?
January 2013 to January 2015

Who is funding the study?
1. National Natural Science Foundation of Zhejiang Province (China)
2. National Public Welfare Industry (China)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
2013zjtcm-031

Study information

Scientific Title
The auxiliary diagnostic value of fissured tongue on axial and peripheral joint dysfunction in Ankylosing Spondylitis

Study objectives
This study is aim to identity whether fissured tongue (FT) has auxiliary diagnostic value in ankylosing spondylitis (AS).

Ethics approval required
Old ethics approval format

Ethics approval(s)

Zhejiang Chinese Medicine University ethics review board, 01/03/2013, ref: no.2013zjtcm-031

Study design
Observational cohort study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Ankylosing spondylitis

Interventions
Participants are screened and undergo a clinical examination and medical history. All participants are screened for pre-existing disease, such as hypertension, dyslipidemia, diabetes mellitus, and inflammatory bowel disease. Information on the use of medications, including meloxicam, salazosulfapyridine, methotrexatep, folic acid, etanercept, thalidomide, celebrex, and methylprednisolone is retrieved from the medical records. Participants are divided to one of two groups based on if they have a fissured tongue or not.

Fissured tongue group (FT): Participants this in group are assessed at baseline, week 12 and week 24 (for follow up). Participants are assessed for their fissured tongue level. Participants have their pain levels assessed using the axial joint pain (AJP) and peripheral joint pain (PJP) levels scale and the visual analog scale (VAS). Participants also complete a morning stiff sale (SMS) that categorically lists the duration of morning stiffness as no stiffness. The axial and peripheral arthritis levels are assessed by physicians.

Participants also undergo a physical examination and have a blood test to evaluate the complete blood cell count and measurement of blood levels of glucose, creatinine, electrolytes, total cholesterol, low-density lipoprotein cholesterol, high-density lipoprotein (HDL) cholesterol, triglycerides, lipoprotein(a), antistreptolysin O (ASO), erythrocyte sedimentation rate(ESR), and C-reactive protein (CRP).

Disease activity was evaluated with the erythrocyte sedimentation rate (ESR), and C-reactive protein (CRP). Middle-finger-to-floor distance and occiput-to-wall distance was used to evaluate spinal flexibility. Plain radiographs of the axial and peripheral were obtained from participants to determine the progress of axial and peripheral arthritis.

Non-fissue tongue group (NFT): Participants undergo the same testing as the fissured tongue group.

The results from each group are compared to see if fissured tongues have an auxiliary diagnostic value in AS.

Intervention Type
Other

Primary outcome(s)

1. Fissured tongue level is measured using photographs and computer programs at baseline, and week 24
2. Axial joint paint is measured using the visual analog scale, stiff morning time scale (SMS) and physical examinations at baseline, week 12 and week 24
3. Peripheral joint pain level is measured using the visual analog scale, stiff morning time scale (SMS) and physical examination at baseline, week 12 and week 24
4. HLA-B27 is measured using flow cytometry at baseline, week 12 and week 24
5. C-reactive protein level is measured using clinical samples at baseline, week 12 and week 24
6. Radiographic damage is measured using radiography at baseline, week 12 and week 24

Key secondary outcome(s))
There are no secondary outcome measures.

Completion date
09/01/2015

Eligibility

Key inclusion criteria
1. Adults aged 15 to 67 years old
2. Diagnosed with AS (fulfill the modified New York criteria for ankylosing spondylitis)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Obvious fissured tongue existing from childhood
2. Diagnosis of traumatic fissured tongue
3. Reluctance to take tongue photographs

Date of first enrolment
08/01/2013

Date of final enrolment
04/01/2014

Locations

Countries of recruitment
China

Study participating centre
Zhejiang University Of Chinese Medicine
Laboratory Of Immunologic & Rheumatology
Hangzhou
China
310053

Study participating centre
The First Affiliated Hospital of Zhongshan University
Zhejiang University Of Chinese Medicine
The First Affiliated Hospital Of Zhongshan University
Guangzhou
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Study participating centre
The Second Affiliated Hospital Of Zhejiang University Of Medicine
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Sponsor information

Organisation
Zhejiang University Of Chinese Medicine

ROR
https://ror.org/04epb4p87

Funder(s)

Funder type
Research organisation

Funder Name
National Natural Science Foundation of Zhejiang Province

Funder Name
National Public Welfare Industry

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from zcmuclinic@zcmu.edu.cn

IPD sharing plan summary
Other

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