

The auxiliary diagnostic value of fissured tongue in Ankylosing Spondylitis

Submission date 13/04/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 03/05/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 10/08/2017	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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.2013zjtc-m-031

Study design

Observational cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Diagnostic

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

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, methotrexate, 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 in this 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 stiffness scale (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-fissure 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 measure

1. Fissured tongue level is measured using photographs and computer programs at baseline, and week 24
2. Axial joint pain 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

Secondary outcome measures

There are no secondary outcome measures.

Overall study start date

06/01/2013

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

Age group

Adult

Sex

Both

Target number of participants

A total of 119 patients (33.3 ± 10.6 years old) were recruited with a median symptom duration of 6.0 years.

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

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Sponsor type

University/education

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**Publication and dissemination plan**

Planned publication in a high-impact peer reviewed journal.

Intention to publish date

06/01/2017

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