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Early screening and warning research on adolescent idiopathic scoliosis in China

Submission date
19/12/2025

Recruitment status
Recruiting

Registration date
19/12/2025

Overall study status
Ongoing

Last Edited
19/12/2025

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Adolescent Idiopathic Scoliosis (AIS) is a condition where the spine curves abnormally during adolescence. It affects many young people worldwide and can lead to serious disability if not treated early. Unfortunately, it is often missed in the early stages. This study aims to create a large group (called a cohort) of young people with and without AIS to better understand the condition. Researchers will collect detailed information, including medical tests, imaging, and blood samples, and use this data to build an early warning system. This system will combine traditional Chinese medicine and Western medicine approaches to help doctors diagnose and treat AIS earlier and more effectively.

Who can participate?
Young people aged 10 to 18 years who have AIS or do not have AIS can take part. There is no restriction on whether they are male or female.

What does the study involve?
This is an observational study, which means participants will not receive experimental treatment. Instead, researchers will monitor participants over time and collect information through tests, questionnaires, and follow-up visits.

What are the possible benefits and risks of participating?
Benefits include free physical exams, free assessments of back muscles, health education, and regular follow-up for 12 months. Risks and inconveniences include the time needed for hospital visits and tests, and the possibility that the condition may worsen during the study. If any problems occur, researchers will provide appropriate medical care. If the condition gets worse quickly, treatment will be offered.

Where is the study run from?
The study is being carried out at several hospitals in China, including Wangjing Hospital of the China Academy of Chinese Medical Sciences, Hebei Provincial Hospital of Traditional Chinese Medicine, and the Affiliated Hospital of Neck, Shoulder, Waist and Leg Pain of Shandong First Medical University.

When is the study starting and how long is it expected to run for?
The first participant will join around January 15, 2026. The last participant will join by June 1, 2028, and the study will finish on October 31, 2028.

Who is funding the study?
The study is funded by the National Key Research and Development Program of China (Grant No.: 2024YFC3507405).

Who is the main contact?
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Additional identifiers

Study information

Scientific Title
Multicenter screening and disease-syndrome combined early warning research on adolescent idiopathic scoliosis in China

Acronym
AIS-ESW

Study objectives
Adolescent Idiopathic Scoliosis (AIS) is a major cause of disability among adolescents worldwide, characterized by high incidence, high progression rate, high disability rate, low awareness rate, and low early diagnosis rate, imposing a heavy socioeconomic burden. Early identification of high-risk groups and patients, risk early warning, precise management, and efficient treatment are key clinical issues urgently needing resolution for this disease. However, there is currently a lack of supporting disease-specific cohorts and early warning systems to meet the significant needs of clinical diagnosis, treatment, and scientific research for AIS. Guided by clinical problems, this study will recruit eligible "diseased" and "un-diseased" AIS subjects from multiple clinical institutions to establish a population cohort. A comprehensive set of macro, meso, and micro indicators will be systematically collected from subjects, including clinical characteristics, patient-reported outcome measures, TCM four diagnostic methods, TCM syndromes, TCM constitutions, imaging data, biomechanical parameters, and blood samples. Following internationally recognized methods and procedures for predictive model construction, a syndrome-disease combined early warning system integrating traditional Chinese and Western medicine multimodal information will be established. This system aims to support the screening, diagnosis, treatment, and scientific research of AIS, and contribute to the implementation and advancement of the Healthy China Strategy.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 29/10/2025, Medical Ethics Committee of Wangjing Hospital of China Academy of Chinese Medical Sciences (Wangjing Hospital of China Academy of Chinese Medical Sciences, No. 6 Wangjing Zhonghuan South Road, Chaoyang District, Beijing, 100102, China; +86 10-84739681; 2454142594@qq.com), ref: WJEC-KT-2025-055-P001

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)

Health condition(s) or problem(s) studied
Early screening and warning on adolescent idiopathic scoliosis

Interventions
This is a multicenter observational cohort study conducted under the National Key R&D Program of China (Grant No.: 2024YFC3507405), led by Wangjing Hospital of China Academy of Chinese Medical Sciences.
A total of 2000 adolescents aged 10–18 years will be recruited from scoliosis-specialized outpatient clinics of participating centers, including those with Adolescent Idiopathic Scoliosis (AIS, "diseased" group) and individuals at risk of developing AIS ("un-diseased" group). All participants or their legal guardians will provide written informed consent prior to study enrollment.

Data collection will be conducted at three time points: baseline, 6 months, and 12 months after enrollment. A comprehensive set of indicators will be systematically collected, covering three levels: macro indicators (demographic data, lifestyle factors, physical examinations, patient-reported outcomes, and Traditional Chinese Medicine-related information including four diagnostic methods, syndromes, and constitution), meso indicators (standing full-spine X-ray assessments and paraspinal muscle function evaluations via surface electromyography), and micro indicators (serum samples for transcriptomic, metabolomic, and proteomic analyqses to identify potential biomarkers).

Following data preprocessing (structuring, standardization, and feature selection), multiple machine learning algorithms will be applied to construct a syndrome-disease combined early warning model integrating Traditional Chinese Medicine and Western medicine multimodal information, in accordance with the international TRIPOD statement. The model will be validated internally (using 30% of the dataset and 10-fold cross-validation) and externally (using data from one independent participating center), with performance evaluated by discrimination, calibration, and clinical utility.

Strict quality control measures will be implemented throughout the study, including standardized training for researchers, regular calibration of detection equipment, periodic on-site monitoring by the leading center, quality control for laboratory tests, and targeted strategies to improve participant follow-up adherence.

Intervention Type
Other

Primary outcome(s)
1. Health-related quality of life measured using the Scoliosis Research Society-22 Patient Questionnaire at baseline, 6 months, and 12 months after enrollment

2. Traditional Chinese medicine characteristics measured using traditional Chinese medicine four diagnostic methods at baseline, 6 months, and 12 months after enrollment

3. Traditional Chinese medicine characteristics measured using traditional Chinese medicine syndrome scale at baseline, 6 months, and 12 months after enrollment

4. Traditional Chinese medicine characteristics measured using Traditional Chinese medicine constitution scale at baseline, 6 months, and 12 months after enrollment

5. Cobb angle measured using standing full-spine X-ray film at baseline, 6 months, and 12 months after enrollment

6. Paraspinal muscle morphology and function measured using surface electromyography at baseline, 6 months, and 12 months after enrollment

7. Potential biomarkers measured using serum samples for transcriptomic, metabolomic, and proteomic analyses at baseline, 6 months, and 12 months after enrollment

Key secondary outcome(s))

Completion date
31/10/2028

Eligibility

Key inclusion criteria
Subjects with adolescent idiopathic scoliosis:
1. According to the diagnostic criteria of the Scoliosis Research Society (SRS), scoliosis is defined as a condition where the Cobb angle measured on a standing full-spine coronal X-ray film is ≥ 10°.
2. Aged 10–18 years.
3. Cobb angle between 10° and 45°, including mild scoliosis (10° ≤ Cobb angle < 20°) and moderate scoliosis (20° ≤ Cobb angle < 45°).
4. Risser sign grade 0–4.
5. Informed consent signed by the subject or their guardian.
6. No scoliosis-specific treatment received in the past 3 months.

Healthy volunteers:
1. Cobb angle < 10°.
2. Aged 10–18 years.
3. Informed consent signed by the subject or their guardian.
4. No participation in other clinical studies in the past 3 months.

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
10 years

Upper age limit
18 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Secondary scoliosis, such as congenital scoliosis and neuromuscular scoliosis.
2. Comorbidity with severe systemic diseases, including those of the cardiovascular, cerebrovascular, liver, and kidney systems.
3. Spinal lesions, such as fractures, tumors, and tuberculosis.
4. Mental illness or cognitive impairment that prevents cooperation with treatment and evaluation.

Date of first enrolment
15/01/2026

Date of final enrolment
01/06/2028

Locations

Countries of recruitment
China

Sponsor information

Organisation
Ministry of Science and Technology of the People's Republic of China

ROR
https://ror.org/027s68j25

Funder(s)

Funder type

Funder Name
Ministry of Science and Technology of the People's Republic of China

Alternative Name(s)
Chinese Ministry of Science and Technology, Ministry of Science & Technology, People Republic of China, , Ministry of Science and Technology (China), State Science and Technology Commission, MOST

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available