

# Chiropractic Manipulation in Adolescent Idiopathic Scoliosis: a pilot study

**Submission date**  
05/04/2005

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
08/04/2005

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
15/02/2008

**Condition category**  
Musculoskeletal Diseases

☐ Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr Dale Rowe

### Contact details

1000 Oakland Drive  
Kalamazoo  
United States of America  
49008

## Additional identifiers

### Protocol serial number

N/A

## Study information

### Scientific Title

### Acronym

MSU-AIS

### Study objectives

A large scale, multi-disciplinary, collaborative clinical trial is needed to explore the effectiveness of chiropractic manipulation of patients with Adolescent Idiopathic Scoliosis (AIS). But prior to conducting such a trial, we needed to perform a pilot randomised controlled trial to explore issues of safety, patient recruitment and compliance, treatment standardisation, sham treatment refinement, inter-professional cooperation, quality assurance, outcome measure selection and statistical analysis.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

The Institutional Review Board of Borgess Medical Center, Kalamazoo approved the study protocol.

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Adolescent Idiopathic Scoliosis (AIS)

### **Interventions**

Patients were treated for six months by:

1. Standard medical care (observation or brace treatment)
2. Standard medical care plus chiropractic manipulation
3. Standard medical care plus sham manipulation

### **Intervention Type**

Other

### **Phase**

Not Specified

### **Primary outcome(s)**

The primary outcome measure was Cobb, and the psychosocial measure was Scoliosis Quality of Life Index.

### **Key secondary outcome(s)**

Not provided at time of registration

### **Completion date**

31/08/2003

## **Eligibility**

**Key inclusion criteria**

1. Children aged 10 - 16 years
2. Diagnosis of Adolescent Idiopathic Scoliosis
3. Spinal curvature on Posterior/Anterior (P/A) radiographs of between 20 and 30 degrees measured by the Cobb method in non-braced individuals and 30 to 40 degrees in braced individuals
4. Palpatory evidence of subluxation (manipulative lesion) on chiropractic screening examination
5. No contraindications to spinal manipulative therapy
6. Signed informed consent by parent/guardian
7. Signed child assent form
8. Availability for follow-up evaluation

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

10 years

**Upper age limit**

16 years

**Sex**

All

**Key exclusion criteria**

1. Age less than 10 or greater than 16 years
2. Diagnosis other than AIS following clinical, radiographic and advanced imaging assessment
3. Contraindications to manipulation
4. Congenital or acquired structural spinal abnormalities
5. Leg length inequality greater than 3/8 inch
6. Pregnancy
7. Pain as a primary clinical feature
8. Mentally incapacitated patient
9. Planning to move/unwilling to return for follow-up
10. Previous back surgery
11. Significant trauma
12. Obesity impairing ability to manipulate

**Date of first enrolment**

01/08/2001

**Date of final enrolment**

31/08/2003

# Locations

## Countries of recruitment

United States of America

## Study participating centre

1000 Oakland Drive

Kalamazoo

United States of America

49008

# Sponsor information

## Organisation

Michigan State University (USA) - Kalamazoo Center for Medical Studies

## ROR

<https://ror.org/05hs6h993>

# Funder(s)

## Funder type

University/education

## Funder Name

Michigan State University (USA)

## Funder Name

Kalamazoo Center for Medical Studies, Kalamazoo, Michigan (USA)

## Funder Name

American Chiropractic Scoliosis Foundation, Fort Collins, Colorado (USA)

## Funder Name

Canadian Memorial Chiropractic College, Toronto (Canada)

# 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?
<a href="#">Results article</a>	Results	21/08/2006		Yes	No