

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

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Contact details

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United States of America
49008

Additional identifiers

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.

Primary study design

Interventional

Study design

Randomised controlled trial

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?
Results article	Results	21/08/2006		Yes	No