

Chiropractic Manipulation in Adolescent Idiopathic Scoliosis: a pilot study

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| Submission date 05/04/2005 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 08/04/2005 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| Last Edited 15/02/2008 | Condition category Musculoskeletal Diseases | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet**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 measure

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

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/08/2001

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

Age group

Child

Lower age limit

10 Years

Upper age limit

16 Years

Sex

Both

Target number of participants

6

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

Sponsor details

1000 Oakland Drive

Kalamazoo

United States of America

49008

Sponsor type

University/education

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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 |