ISRCTN71590683 https://doi.org/10.1186/ISRCTN71590683

Scoliosis correction force measurement study

Submission date	Recruitment status	[ ] Prospectively registered
30/06/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/08/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
07/04/2016	Musculoskeletal Diseases	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims.
Adolescent Idiopathic Scoliosis (AIS) is a condition that causes the spine to curve sideways. It can be treated with surgery to correct the curvature, where the spine is straightened using rods attached to the spine by screws, hooks and/or wires. The aim of this study is to find out how much force is required to move the spine to midline. We also wish to find out how much spine movement can be achieved with a maximum force of 40 lbs at one point of attachment.

Who can participate?
Patients between 8 and 16 years old with idiopathic scoliosis (curvature of the spine with no known cause) with a single curve requiring surgical treatment via a posterior (back) only surgical approach.

What does the study involve?
While the patient is undergoing surgery, force measurements are taken to determine the force necessary to move the patient's curved spine toward midline, and the amount of curve correction at a maximum of 40 lbs of force. This takes about 10 minutes. After these measurements are taken, no follow up is required.

What are the possible benefits and risks of participating?
The risks were considered to be very low, but as with all surgeries, it is possible that some risks could develop. The main risk was that while pulling the spine toward the middle of your back, the cable, screw or rod could break or dislodge and cause damage to nerves, bone or muscle. The force used to pull the spine toward the middle will be applied gradually to minimize this risk.

Where is the study run from?
Royal National Orthopaedic Hospital (UK)

When is the study starting and how long is it expected to run for?
July 2009 to September 2009

Who is funding the study?
Kspine Inc. (USA)

Who is the main contact?
Diane Burnside

Contact information

Type(s)
Scientific

Contact name
Mr Hilali Noordeen

Contact details
27 Harley Street
London
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Kspine 101

Study information

Scientific Title
A non-randomised study to measure the force required to move the spine towards midline in adolescent idiopathic scoliosis patients

Study objectives
This study will measure the force required to move the spine toward midline in patients with adolescent idiopathic scoliosis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East London and The City/Research Ethics Committee 1, 01/07/2009, ref: 09/H0703/70

Study design
Non-randomised study

Primary study design

Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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
Adolescent idiopathic scoliosis (AIS)

Interventions
Force measurements will be taken to determine the force necessary to move a curved spine toward midline. The total duration of treatment for this study will be approximately 10 minutes. After these measurements are taken, no follow up is required.

Intervention Type
Procedure/Surgery

Primary outcome measure
Force measurements to determine the force necessary to move a curved spine toward midline, measured near the beginning of the surgery and completed before the surgery to correct the patient's scoliosis is begun.

Secondary outcome measures
Amount of curve correction at a maximum of 40 lbs of force, measured near the beginning of the surgery and completed before the surgery to correct the patient's scoliosis is begun.

Overall study start date
13/07/2009

Completion date
29/09/2009

Eligibility

Key inclusion criteria
1. Patient has idiopathic scoliosis with a single curve requiring surgical treatment via a posterior only surgical approach
2. The curve appears to be compliant as evidenced by standing bending x-rays and/or the ability of the surgeon to improve the curve with external manipulation
3. Patient must be between 8 and 16 years old, either sex

Participant type(s)
Patient

Age group
Child

Lower age limit
8 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Patient has an underlying neurologic or congenital pathology involving the spine in addition to idiopathic scoliosis
2. Patient has local or systemic infection
3. Patient is participating in any other device or drug study
4. Patient is grossly obese with a body mass index greater than 40 kg/m^2
5. Patient has a history of communicable disease such as human immunodeficiency virus (HIV), hepatitis, etc.

Date of first enrolment
13/07/2009

Date of final enrolment
29/09/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
27 Harley Street
London
United Kingdom
W1G 9QP

Sponsor information

Organisation
Kspine, Inc. (USA)

Sponsor details
5610 Rowland Rd
Suite 110
Minnetonka, MN
United States of America
55124

Sponsor type
Industry

ROR
https://ror.org/00mwvbx98

Funder(s)

Funder type
Industry

Funder Name
Kspine, Inc. (USA)

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?
HRA research summary			28/06/2023	No	No