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Fusionless treatment of idiopathic scoliosis with the MIScoli® system during the growth period (FUTURE 2)

Submission date
14/11/2023

Recruitment status
Suspended

Registration date
16/11/2023

Overall study status
Suspended

Last Edited
10/05/2024

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Juvenile and adolescent idiopathic scoliosis (AIS) is a structural three-dimensional deformity of the spine of greater than 10° that is accompanied by torsion of the spinal column. It is detected during late childhood or early adolescence. AIS is the most common type of scoliosis and affects 1% to 3% of children aged 10 to 16. Approximately 70% of curves in patients with juvenile (10 years old) idiopathic scoliosis progress and require surgery. The angle measured on the standing frontal radiograph according to the Cobb method is one of the decisive factors in managing idiopathic scoliosis, and it is directly correlated to all treatment decisions. Subjects with Cobb angles exceeding 40°- 45° are candidates for surgical intervention. Subjects with curves greater than 30° with attempted and failed brace treatment may also be surgical candidates if significant growth remains. According to the Scoliosis Research Society (SRS), the current standard of care for AIS patients falls into three main categories (observation, bracing, and surgery), and is based on the risk of curve progression: observation is generally recommended for skeletal immature (with remaining growth) patients whose Cobb angles are less than 25°, or for skeletal mature patients with Cobb angles less than 50°; bracing is typically used on skeletal immature patients with Cobb angles in between 25° and 40°, with the goal of the brace is to prevent the curve from worsening; and, surgical treatment is typically indicated for skeletal immature patients whose Cobb angles are greater than 45°, or for patients with Cobb angle greater than 50° when growth has stopped. The goal of surgical treatment is two-fold: firstly, to prevent curve progression and secondly to obtain some curve correction. Surgical treatment today utilizes metal implants which are attached to the spine and then connected to one or two rods. Implants are used to correct the spine and hold the spine in the corrected position until the instrumented spine segments are completely fused to form a single bone.

Who can participate?
Male and female subjects greater than 8 years of age with juvenile or AIS with significant growth remaining and a major curve greater than 40° and less than 70° are at high risk for progression. Subjects with a major curve greater than 30º who failed brace treatment may also be considered.

What does the study involve?
This study in Canada aims to include 30 participants who will undergo the implantation of the MIScoli® system. The study will assess skeletal maturity, curve progression, pain, and a questionnaire used to evaluate health-related quality of life for young people with AIS at various points over a 24-month period, with additional follow-ups if needed. The MIScoli® system is designed for fixing and securing the convex side of thoracic curvatures in growing children /adolescents with high-risk idiopathic scoliosis. It aims to reduce deformity and prevent progression while preserving motion. The device is intended for use in individuals over 8 years old, with significant growth remaining, and specific scoliosis criteria. The study will monitor adverse events, neurological status, and device integrity at each visit.

What are the possible benefits and risks of participating?
Benefits and risks not provided at registration

Where is the study run from?
Spino Modulation (Canada)

When is the study starting and how long is it expected to run for?
October 2023 to April 2027

Who is funding the study?
Spino Modulation (Canada)

Who is the main contact?
Agapi Bolanakis, abolanakis@spinologics.com

Contact information

Type(s)
Principal investigator

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Additional identifiers

Protocol serial number
SM-0001-PRO/FUTURE 2

Study information

Scientific Title
SM-0001-PRO: Safety and probable benefit of the MIScoli® system compared to the SCOLI-TETHER system in the fusionless treatment of juvenile and adolescent idiopathic scoliosis during the growth period

Acronym
FUTURE 2

Study objectives
Although fusion surgery is the only form of treatment that provides the lasting reduction of a deformed spine (idiopathic scoliosis), it does so at the expense of spinal motion. Also, fusion done early in the adolescent growth spurt may significantly limit growth. A new treatment that provides lasting control of the curve without these limitations would be a meaningful addition to the armamentarium of surgical treatments for adolescent idiopathic scoliosis (AIS).

This research study involves using an investigational medical device, called MIScoli® (internal bracing). The system is being developed for the treatment of idiopathic scoliosis (scoliosis for which the cause is unknown), to reduce deformity and prevent its worsening in growing children /adolescents at high risk for curve progression while preserving motion. The MIScoli® uses screws to attach to the spine’s bone growth on the curved side so that as your child grows the curve may stop progressing or improve. The MIScoli® was used in Special Access Cases in Canada. It is not available for use by doctors because it is not yet approved for use. Health Canada has reviewed and approved the use of the MIScoli® in this clinical trial.

The goal of the study is to compare the safety and probable benefit of the MIScoli® system to the previous generation of the device, called the SCOLI-TETHER system, for the treatment of juveniles and AIS.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/12/2023, The Children's Hospital of Eastern Ontario reseach Ethics Board (401 Smyth Road Room R2110, Reacher Institute Building 2, Ottawa Onatrio, K1H 8L1, Canada; +1 613.737.7600; nanderson@cheo.on.ca), ref: 23/12E

Primary study design
Interventional

Study design
Multicentre single-arm prospective study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Juvenile or adolescent idiopathic scoliosis

Interventions
This multicentre, single-arm, prospective study will enrol 30 subjects in Canada, each of whom will have the MIScoli® system implanted. Subjects with a successfully implanted investigational device will undergo an assessment of skeletal maturity, curve evolution, pain, and SRS-22r scores. Study visits will be done pre-operatively, on the day of surgery, prior to discharge, at Visit 4 / 6 weeks, Visit 5 / 6 months, Visit 6 / 12 months, Visit 7 / 18 months, and Visit 8 / 24 months. If skeletal maturity is not reached by Visit 8 / 24 months postimplantation, subjects will be followed yearly until the end of study definition is reached. Subjects will be assessed at each study visit for adverse events, neurological status, and device integrity.

The MIScoli® system is intended for anterolateral vertebral body fixation and internal fastening of the convex side of the thoracic curvatures, thereby reducing the deformity and preventing the progression of idiopathic scoliosis in growing children/adolescents at high risk for curve progression, while preserving motion. This device is intended for use in subjects greater than 8 years of age with significant growth remaining, who have scoliosis with Cobb Angle greater than 40° and Lenke I, II and V curve pattern. Subjects with curves greater than 30° with attempted but failed brace treatment are also potential candidates for the procedure. The MIScoli® system is intended to be used at contiguous vertebral levels through an anterior thoracoscopic or open

technique between T4 and L4 inclusively. The device is intended to treat major thoracic scoliosis in subjects who have less than 50° of thoracic kyphosis (T5-T12), Risser stage of 0 or 1, and Sanders score of less than or equal to 5.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
MIScoli® System

Primary outcome(s)
1. Major Cobb angle measured using X-ray readings is less than or equal to 40° at Visit 8 / 24 months AND freedom from treatment-related SAE measured using medical records up to 24 months post-implantation
2. Rate of treatment-related SAE up to 24 months post-implantation
3. Major Cobb angle measured using X-ray readings of less than or equal to 40° at Visit 8 / 24 months postimplantation

Key secondary outcome(s)
1. Rate of suspected tether breakage adverse events measured using medical records up to 6, 12, 18 and 24 months post-implantation
2. Health-Related Quality of Life (HRQoL) measured using the SRS-22r questionnaire at Visit 1 / Pre-op to each follow-up visit until Visit 8 / 24 months
3. Back pain measured using a Visual Analog Scale (VAS) at Visit 1 / Pre-op to each follow-up visit until Visit 8 / 24 months
4. Instrumented Cobb angle measured using X-ray readings of a change of 6° or more from Visit 4 / 6 weeks to each follow-up visit until Visit 8 / 24 months
5. Instrumented Cobb angle change measured using X-ray readings from Visit 4 / 6 weeks to each follow-up visit until Visit 8 / 24 months
6. Major Cobb angle measured using X-ray readings less than or equal to 40° at Visit 8 / 24 months post-implantation AND no revision surgery up to 12 months postimplantation AND up to one revision surgery between 12 months and 24 months postimplantation AND freedom from subsequent reoperation up to 24 months post-implantation.
7. Constant Cobb angle measured using X-ray readings less than or equal to 40° at Visit 8 / 24 months post-implantation AND no revision surgery up to 12 months postimplantation AND up to one revision surgery between 12 months and 24 months postimplantation AND freedom from subsequent reoperation up to 24 months post-implantation.
8. Instrumented Cobb angle measured using X-ray readings less than or equal to 40° at Visit 8 / 24 months post-implantation AND no revision surgery up to 12 months post-implantation AND up to one revision surgery between 12 months and 24 months post-implantation AND freedom from subsequent reoperation up to 24 months post-implantation.

Completion date
04/04/2027

Eligibility

Key inclusion criteria

Candidates for this study must meet ALL of the following criteria:
1. Diagnosis of juvenile or adolescent idiopathic scoliosis
2. Male or female subjects greater than 8 years of age with significant growth remaining
3. European Risser Stage 0 or 1 and Sanders score less than or equal to (≤) 5, at Visit 1
4. Major scoliosis with Cobb angle > 40° and < 70° and Lenke I, II or V curve pattern. Cobb angle measurements refer to measures taken without a brace. Subjects with Cobb angle >30° with attempted but failed brace treatment. Failure of brace treatment is defined as greater than (>) 5° of progression and/or intolerance to brace wear
5. Thoracic kyphosis (T5-T12) < 50°. 6. Instrumentation to be applied no more cephalad than T4 and no more caudal than L4 (inclusive)
7. The subject must be physically and mentally willing and able to comply with the study visit schedule and all protocol requirements
8. Subject assent and parent/legal guardian consent obtained and documented

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
8 Years

Upper age limit
18 Years

Sex
All

Key exclusion criteria
Candidates will be excluded from the study if ANY of the following apply:
1. The vertebrae to be instrumented are less than 12mm in height (based on the MIScoli® staple size)
2. One of the vertebrae to be instrumented in less than 20.5mm in width (based on the smallest MIScoli® screw length)
3. One of the vertebrae to be instrumented is more than 44mm in width (based on the longest MIScoli® screw length)
4. Diagnosis of non-idiopathic scoliosis
5. Menarche onset > 4 months at Visit 1
6. Non-ambulatory
7. Clinical diagnosis of osteoporosis, osteopenia, osteomalacia, Paget’s disease or metabolic bone disease
8. Prior thoracic surgery for any reason
9. Abnormal neurological exam for any reason at Visit 1
10. Enrollment in an active drug or device trial that is more than minimal risk and where participation in the trial would confound the measurements for the present study
11. Enrollment in a device trial for the efficacy of a musculoskeletal device and where participation in the trial would confound the measurements for the present study

12. Less than 30 days from completion of another clinical trial of more than minimal risk or for assessment safety and efficacy 13. Any condition or therapy that the investigator believes might pose a risk to the participant or make participation in the study not in the participant’s best interest

Date of first enrolment
19/11/2023

Date of final enrolment
30/01/2025

Locations

Countries of recruitment
Canada

Study participating centre
CHU Sainte-Justine Hospital
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Study participating centre
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Sponsor information

Organisation
Spino Modulation

Funder(s)

Funder type
Industry

Funder Name
Spino Modulation Inc

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication