ISRCTN10892409 https://doi.org/10.1186/ISRCTN10892409

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

Submission date
12/03/2019

Recruitment status
No longer recruiting

Registration date
18/03/2019

Overall study status
Completed

Last Edited
15/11/2023

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

Current plain English summary as of 27/10/2021:

Background and study aims
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 the use of an investigational medical device, called MIScoli™ system (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™ system 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™ system was used only in a group of five female subjects in a clinical pilot study conducted in Singapore and it was observed that the use of this system to address idiopathic thoracic scoliosis was effective and safe. 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™ system in this clinical trial.

Who can participate?
Children aged over 8 with idiopathic scoliosis who have at least three years of estimated growth remaining.

What does the study involve?
The purpose of this clinical study is to demonstrate that the MIScoli™ system is safe for use and shows probable benefit by stopping the progression of the major curve (Cobb angle) of a scoliosis in growing children and adolescents when compared to their initial curvature.

What are the possible benefits and risks of participating?
Any research study has potential risks. The medical device and the surgery may have risks and

cause discomfort and inconveniences, some of which may be unknown at this time. The MIScoli™ system might potentially avoid the need for fusion surgery resulting in a greater range of motion and more flexibility. Fusion surgery usually involves an open back incision compared to the small incisions with the MIScoli™ system surgery. This leads to a much shorter recovery time. There may be less risk of infection, less blood loss, and so less need for blood transfusion, increase range of motion and less pain with the MIScoli™ system.

Where is the study run from?
The study is being held in 4 different locations throughout Canada.
1. Sainte-Justine Hospital in Montreal, Quebec
2. The Montreal Children's Hospital in Montreal, Quebec
3. The Children's Hospital of Eastern Ontario in Ottawa, Ontario
4. British Columbia's Children's Hospital in Vancouver, BC
5. IWK Health in Nova Scotia

When is the study starting and how long is it expected to run for?
June 2017 to September 2023

Who is funding the study?
Spino Modulation Inc (Canada)

Who is the main contact?
Dr Firoz Miyanji, fmiyanji@cw.bc.ca
Dr Kevin Smit, KSmit@cheo.on.ca

Previous plain English summary:

Background and study aims
Although 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 AIS.
This research study involves the use of an investigational medical device, called SCOLITETHER (MIScoli) System (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 SCOLIOTETHER system 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 SCOLITETHER system was used only in a group of five female subjects in a clinical pilot study conducted in Singapore and it was observed that the use of this system to address idiopathic thoracic scoliosis was effective and safe. 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 SCOLITETHER system in this clinical trial.

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When is the study starting and how long is it expected to run for?
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1. Sainte-Justine Hospital in Montreal, Quebec
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4. British Columbia's Children's Hospital in Vancouver, BC
5. IWK Health in Nova Scotia

Who is the main contact?
Dr Firoz Miyanji, fmiyanji@cw.bc.ca
Dr Kevin Smit, KSmit@cheo.on.ca

Contact information

Type(s)
Scientific

Contact name
Dr Kevin Smit

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Type(s)
Scientific

Contact name
Dr Firoz Miyanji

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CD-0001-PRO/FUTURE

Study information

Scientific Title
Fusionless treatment of idiopathic scoliosis with the MIScoli™ system during the growth period (FUTURE)

Acronym
FUTURE

Study objectives
Current Study Hypothesis as of 27/10/2021:

The MIScoli™ system shows benefit to halt the progression of the major curve of scoliosis reflected by a decrease in the Cobb angle from Visit 1 / Pre-Op baseline to Visit 6 / 1 Year.

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Previous Study hypothesis:
The SCOLI-TETHER system shows benefit to halt the progression of the major curve of scoliosis reflected by a decrease in the Cobb angle compared to baseline.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Current ethics approval as of 25/01/2021:

1. Approved 21/07/2020, Le CHU Sainte-Justine (3175, Chemin de la Côte-Sainte-Catherine, Montreal, Quebec, Canada, H3T 1C5)
2. Approved 06/05/2019, The Montreal Children's Hospital (1001 Boulevard Décarie, Montreal, Quebec, Canada, H4A 3J1)
3. Approved 21/07/2020, The Children's Hospital of Eastern Ontario Research Ethics Board (401 Smyth Road, Room R2110, CHEO Research Institute Building 2, Ottawa, Ontario, K1H 8L1; 613-737-7600 ext.3350; nanderson@cheo.on.ca), ref: 18/17E
4. Approved 26/06/2020, British Columbia's Children's Hospital (4480 Oak Street, Vancouver, British-Columbia, Canada, V6H 3V4), ref: UBC C&W NUMBER:H18-02322
5. Approved 15/07/2020, IWK Health (5850 University Avenue, PO Box 9700, Halifax, Nova Scotia, Canada, B3K 6R8)

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Previous ethics approval:

Site 01 – Approved 06/05/2019, Le CHU Sainte-Justine (3175, Chemin de la Côte-Sainte-Catherine, Montreal, Quebec, Canada, H3T 1C5)
Site 02 – Approved 20/06/2019, The Montreal Children's Hospital (1001 Boulevard Décarie, Montreal, Quebec, Canada, H4A 3J1)
Site 03 – Approved 19/02/2019, The Children's Hospital of Eastern Ontario Research Ethics Board (401 Smyth Road, Room R2110, CHEO Research Institute Building 2, Ottawa, Ontario, K1H 8L1; 613-737-7600 ext.3350; nanderson@cheo.on.ca), ref: 18/17E
Site 04 – Approved 23/01/2019, British Columbia's Children's Hospital (4480 Oak Street, Vancouver, British-Columbia, Canada, V6H 3V4), ref: UBC C&W NUMBER:H18-02322
Site 05 – Approved 27/02/2020, IWK Health (5850 University Avenue, PO Box 9700, Halifax, Nova Scotia, Canada, B3K 6R8)

Study design
Multicentre single-arm interventional 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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Current condition as of 27/10/2021:

Major thoracic scoliosis with Cobb Angle greater than 40° and less than 70° and Lenke I, II or V curve pattern. Children/adolescents with curves greater than 30° with attempted but failed brace treatment are also potential candidates for this study.

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Previous Condition:

Major thoracic scoliosis with Cobb Angle greater than 40° and Lenke I, II and V curve pattern.

Interventions

Current interventions as of 27/10/2021:

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 patients greater than 8 years of age with significant growth remaining who have a major thoracic scoliosis with Cobb Angle greater than 40° and and less than 70°, and Lenke I, II and V curve pattern. Patients with curves greater than 30 degrees with attempted but failed brace treatment are also potential candidates for the procedure. It is intended to be used at contiguous levels through an anterior thoracoscopic or open technique between T4 and L2 inclusively. The device is intended to treat major thoracic scoliosis in patients who have less than 50° of thoracic kyphosis (T5-T12) and a Risser stage of 0 or 1.

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Previous interventions as of 06/03/2020:

The SCOLI-TETHER (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 patients greater than 8 years of age with significant growth remaining who have a major thoracic scoliosis with Cobb Angle greater than 40° and Lenke I, II and V curve pattern. Patients with curves greater than 30 degrees with attempted but failed brace treatment are also potential candidates for the procedure. It is intended to be used at contiguous levels through an anterior thoracoscopic or open technique between T4 and L2 inclusively. The device is intended to treat major thoracic scoliosis in patients who have less than 50° of thoracic kyphosis (T5-T12) and a Risser stage of 0 or 1.

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Previous interventions:

The SCOLI-TETHER (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 patients 8-13 years of age who have a major thoracic scoliosis with Cobb Angle greater than 40° and Lenke

I, II and V curve pattern. It is intended to be used at contiguous levels through an anterior thoracoscopic or open technique between T4 and L2 inclusively. The device is intended to treat major thoracic scoliosis in patients who have less than 50° of thoracic kyphosis (T5-T12) and a Risser stage of 0 or 1.

X-rays will be taken to monitor the progress from baseline to 5-year follow-up. The x-ray will take place at the participant's local participating hospital and reviewed by an independent laboratory different from the hospital.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
MIScoli™

Primary outcome measure
Current primary outcome measure as of 27/10/2021:

Benefit of MIScoli™ system in halting the progression of the major curve (Cobb angle) of scoliosis in growing subject measured by examination of x-rays at baseline and 3-year follow-up. The x-rays will be reviewed by an independent contract laboratory organization.

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Previous primary outcome measure as of 25/01/2021:

Benefit of SCOLI-TETHER System in halting the progression of the major curve (Cobb angle) of scoliosis in growing subject measured by examination of x-rays at baseline and 3-year follow-up. The x-rays will be reviewed by an independent contract laboratory organization.

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Previous primary outcome measure:

Benefit of SCOLI-TETHER System in halting the progression of the major curve (Cobb angle) of scoliosis in growing subject measured by examination of x-rays at baseline and 5-year follow-up. The x-rays will be reviewed by an independent contract laboratory organization

Secondary outcome measures
Current secondary outcome measures as of 27/10/2021:

Quality of life of the subjects that were treated with the MIScoli™ system measured using SRS-30 questionnaire at 3 year follow-up.

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Previous secondary outcome measures as of 25/01/2021:

Quality of life of the subjects that were treated with the SCOLI-TETHER System measured using SRS-30 questionnaire at 3 year follow-up

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Previous secondary outcome measures:

Quality of life of the subjects that were treated with the SCOLI-TETHER System measured using SRS-30 questionnaire at 5 year follow-up

Overall study start date
01/06/2017

Completion date
01/09/2023

Eligibility

Key inclusion criteria
Current inclusion criteria as of 27/10/2021:

1. Diagnosis of juvenile or adolescent idiopathic scoliosis
2. Male and female subjects greater than 8 years of age with significant growth remaining.
3. Risser Stage 0 or 1 at Visit 1.
4. Subjects should have at least three years of estimated growth remaining based on European Risser
staging.
5. Major thoracic 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 curves greater than 30° with attempted but failed brace treatment are also potential candidates for this study.
6. Thoracic kyphosis (T5-T12) < 50°
7. Instrumentation to be applied no more cephalad than T4 and no more caudal than L2 (inclusive)
8. Menses < 4 months at Visit 1
9. Subject must be physically and mentally willing and able to comply with the study visit schedule and all
protocol requirements.
10. Subject assent and parent/legal guardian consent obtained and documented.

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Previous inclusion criteria as of 06/03/2020:

1. Diagnosis of juvenile or adolescent idiopathic scoliosis
2. Male and female subjects greater than 8 years of age with significant growth remaining
3. Risser Stage 0 or 1
4. Subjects should have at least three years of estimated growth remaining based on Risser staging

5. Major thoracic scoliosis with Cobb Angle > 40° and < 70° and Lenke I, II or V curve pattern. Cobb measurements refer to measures taken without a brace. Patients with curves greater than 30 degrees with attempted but failed brace treatment are also potential candidates for the procedure
6. Thoracic kyphosis (T5-T12) < 50°
7. Instrumentation to be applied no more cephalad than T4 and no more caudal than L2 (inclusive)
8. Menses < 4 months
9. Subject must be physically and mentally willing and able to comply with postoperative and routinely scheduled clinical and radiographic evaluations
10. Subject assent and parent/legal guardian consent obtained and documented

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Previous inclusion criteria:

1. Diagnosis of juvenile or adolescent idiopathic scoliosis
2. Greater than or equal to 8 and less or equal than 13 years of age
3. Risser Stage 0 or 1
4. Subjects should have at least three years of estimated growth remaining based on Risser staging
5. Major thoracic scoliosis with Cobb Angle > 40° and < 70° and Lenke I, II or V curve pattern. Cobb measurements refer to measures taken without a brace
6. Thoracic kyphosis (T5-T12) < 50°
7. Instrumentation to be applied no more cephalad than T4 and no more caudal than L2 (inclusive)
8. Menses < 4 months
9. Subject must be physically and mentally willing and able to comply with postoperative and routinely scheduled clinical and radiographic evaluations
10. Subject assent and parent/legal guardian consent obtained and documented

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
59

Key exclusion criteria
Current exclusion criteria as of 06/03/2020:

1. Scoliosis curve is less than 30° or more than 70°
2. Thoracic kyphosis is greater than or equal to 50° (T5-T12)
3. The vertebrae to be instrumented is less than 12mm in height (based on the staple size)
4. One of the vertebrae to be instrumented in less than 20.5mm in width (base on smallest screw length)

5. One of the vertebrae to be instrumented is more than 44mm in width (base on longest screw length)
6. Non-idiopathic scoliosis
7. Non-ambulatory
8. Subject with clinical diagnosis of osteoporosis, osteopenia, osteomalacia, Paget's disease and metabolic bone disease
9. Prior thoracic surgery
10. Abnormal neurological status at baseline
11. 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

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Previous exclusion criteria:

1. The vertebrae to be instrumented is less than 12 mm in height (based on the staple size)
2. One of the vertebrae to be instrumented in less than 22 mm in width (base on smallest screw length)
3. One of the vertebrae to be instrumented in more than 44 mm in width (base on longest screw length)
4. Non-idiopathic scoliosis
5. Non-ambulatory
6. Clinical diagnosis of osteoporosis, osteopenia, osteomalacia, Paget's disease and metabolic bone disease
7. Prior thoracic surgery
8. Abnormal neurological status at baseline
9. 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
01/04/2019

Date of final enrolment
02/02/2022

Locations

Countries of recruitment
Canada

Study participating centre
CHU Sainte-Justine Hospital
3175 Chemin de la Cote-Sainte-Catherine
Montreal
Canada
H3T1C5

Study participating centre
The Montreal Children's Hospital
1001 Boulevard Decarie
Montreal
Canada
H4A3J1

Study participating centre
The Children's Hospital of Eastern Ontario
401 Smyth Road
Ottawa
Canada
K1H8L1

Study participating centre
British Columbia's Children's Hospital
4480 Oak Street
Vancouver
Canada
V6H 3V4

Study participating centre
IWK Health
5850 University Avenue
PO Box 9700
Halifax
Canada
B3K 6R8

Sponsor information

Organisation
Spino Modulation Inc

Sponsor details
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Montreal
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+1-888-988-2747
regulatory@spinologics.com

Sponsor type
Industry

Website
https://www.spinologics.com

Funder(s)

Funder type
Industry

Funder Name
Spino Modulation Inc

Results and Publications

Publication and dissemination plan
The results of the trial will be submitted to the Scoliosis Research Society annual meeting and a publication will be submitted to Spine.

Intention to publish date
01/08/2025

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
Other