Longitudinal MRI study to catch EARLY scoliotic changes of the Bone and Intervertebral Disc in younger sisters and daughters of adolescent idiopathic scoliosis patients and in boys and girls of the 22q11.2DS population.

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To longitudinally evaluate the substantial differences in anatomical changes in the spine during adolescent growth in girls, at increased risk for scoliosis development, and in adolescent 22q11.2DS patients, that do and do not develop AIS.

| Ethical review | Approved WMO |
|-----------------------|------------------------|
| Status | Recruiting |
| Health condition type | Other condition |
| Study type | Observational invasive |

Summary

ID

NL-OMON53775

Source ToetsingOnline

Brief title Earlybird

Condition

- Other condition
- Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)

Synonym

3D curve of the spine, curvature of the spine

Health condition

scoliose

Research involving Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht **Source(s) of monetary or material Support:** Subsidie vanuit het Scolistorm project (consortium)

Intervention

Keyword: Growth, MRI, Scoliosis

Outcome measures

Primary outcome

The main study parameter will be the longitudinal changes in segmental axial

rotation on MRI of the thoracolumbar spine in subjects that do and do not

develop AIS.

Secondary outcome

1. Changes in bone and intervertebral disc morphology (A-P, left-right ratio,

torsion, volumes, shift of the nucleus pulposus) during growth.

- 2. Changes in spinal alignment during growth
- 3. Spine specific (IVD/endplates) maturity assessment grading.
- 4. Spine specific maturity assessment grading in relation to:
- o Skeletal maturity (Greulich and Pyle digital skeletal age)
- o Biological maturity (age, menarche, as well as potential markers for

endochondral ossification identified in the future that can be measured on the

samples in the concurrent biobank of this study population (examples are vit D,

serum collagen X matrix, Osteopontin)

o Generalized joint hypermobility (Beighton/Bulbena score)

o Spinal alignment and length in the upright position and supine position

o Spinal cord morphology changes (conus level) during growth

o Chest wall shape development (shape, size and volume)

All above in subjects that do versus those that do not develop scoliosis

Study description

Background summary

The cause of the most common form of scoliosis is not yet known. We do know that it usually occurs in girls during the growth spurt and we suspect that it has to do with the growth of the intervertebral discs and posture during growth spurt. If the bend test is abnormal, the size of the scoliosis can be measured on an X-ray and is expressed in degrees (the Cobb angle, see figure 2). This Cobb angle is used by the orthopedist to monitor the severity of scoliosis. Scoliosis is only diagnosed if the Cobb angle on the X-ray is greater than 10 degrees. Children are monitored at a Cobb angle below 20 degrees. Growing children with a bend above 25 degrees are braced to prevent further increase in scoliosis. If the growth scoliosis increases above 45 degrees, surgery is suggested, as this severe scoliosis can continue to progress for the rest of life.

Study objective

To longitudinally evaluate the substantial differences in anatomical changes in the spine during adolescent growth in girls, at increased risk for scoliosis development, and in adolescent 22q11.2DS patients, that do and do not develop AIS.

Study design

Prospective, obsevational cohory study

Intervention

N/A

Study burden and risks

Participants have a higher risk for development of idiopathic scoliosis compared to their peers and scoliosis can be diagnosed and treated at an early stage. This study can only be done using these patients groups. MR imaging is nonionizing and gives no noteworthy risk. Therefore the risks associated with participating in this study are negligible and the burden minimal.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age Children (2-11 years)

Inclusion criteria

Cohort 1: - Female, - 8, 9 or 10 years old

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- An older sibling, twin or parent diagnosed with AIS

 No clinical signs of scoliosis at inclusion (physical examination by forward bending test and Bunnell Scoliometer assessment with a cut-off value of 7°.
Written informed consent of parents/legal representatives.

Cohort 2:

- Diagnosed with 22q11.2DS
- Girls: 8, 9 or 10 years old.
- Boys: 9, 10 or 11 years old.

- No clinical signs of scoliosis at inclusion (physical examination by forward

bending test and Bunnell Scoliometer assessment with a cut-off value of 7°.

- Written informed consent of parents/legal representatives.

Exclusion criteria

- Contraindications for MR imaging
- Early-onset scoliosis or other spinal deformities
- Other syndromes or neuromuscular disease associated with scoliosis
- Clinical signs of >1cm leg length discrepancy
- Other diseases or injuries, that are related to abnormal spinal growth,

posture, activity levels, or scoliosis development.

Study design

Design

| Study type: Observational invasive | | |
|------------------------------------|-------------------------|--|
| Masking: | Open (masking not used) | |
| Control: | Uncontrolled | |
| Primary purpose: | Basic science | |

Recruitment

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| NL | |
|---------------------------|------------|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 05-06-2023 |
| Enrollment: | 120 |
| Туре: | Actual |

Ethics review

| Approved WMO | |
|--------------------|------------------|
| Date: | 08-03-2023 |
| Application type: | First submission |
| Review commission: | METC NedMec |

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register CCMO **ID** NL82419.041.22